EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE No. 2:12-MD-02327
THIS DOCUMENT RELATES TO	:	MDL 2327
WAVE 4 CASES GYNEMESH PS and PROLIFT	:	JOSEPH R. GOODWIN US DISTRICT JUDGE

- - -

March 12, 2017

- - -

CONFIDENTIAL

Deposition of HARVEY A. WINKLER, M.D., held at Butler Snow LLP, 1700 Broadway, New York, commencing at 4:10 p.m., on the above date, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
Deps@golkow.com

A P P E A R A N C E S:

ZONIES LAW LLC
BY: GREG BENTLEY, ESQUIRE
CHELSEA THOMPSON, ESQUIRE
1900 Wazee Street, Suite 203
Denver, Colorado 80202
720.464.5300
Representing the Plaintiff

BUTLER SNOW LLP
BY: PAUL S. ROSENBLATT, ESQUIRE
1020 Highland Colony Parkway
Suite 1400
Ridgeland, Missouri 39157
601.948.5711
paul.rosenblatt@butlersnow.com
Representing the Defendant

- - -

TRANSCRIPT INDEX

EXHIBITS WITH ORIGINAL TRANSCRIPT

- - -

- - -

E X H I B I T S

- - -

- - -

E X H I B I T S

- - -

Page 8

- - -
4:10 p.m.
New York, New York
- - -

HARVEY A. WINKLER, M.D., the Witness herein, having been first duly sworn by a Notary Public in and of the State of New York, was examined and testified as follows:

- - -

(Exhibit Winkler 1, Amended Notice to Take Deposition of Harvey Winkler, M.D., dated March 9, 2017, was marked for identification, as of this date.)

(Exhibit Winkler 2, Expert Report of Harvey Winkler, M.D. Regarding Gynemesh PS and Prolift, dated February 5, 2017, was marked for identification, as of this date.)

(Exhibit Winkler 3, Curriculum Vitae of Harvey Winkler, M.D., was marked for identification, as of this date.)

Page 9

(Exhibit Winkler 4, Supplemental General Reliance List in Addition to Materials Referenced in Report MDL Wave 4, was marked for identification, as of this date.)

(Exhibit Winkler 5, Invoice No. 1010 of Harvey Winkler, M.D., dated January 17, 2017, was marked for identification, as of this date.)

- - -

EXAMINATION BY
MR. BENTLEY:

Q. Good afternoon, Doctor Winkler. We just finished your deposition regarding your TVT and TVT-Exact report. We're going to start now with your deposition covering your report on Prolift and Gynemesh PS.

Do you understand that?

A. Yes, I do.

Q. For the record, we're marking as Exhibit 1 the Notice of Deposition, which was previously entered in the TVT deposition.

Exhibit 2 is your report regarding Prolift and Gynemesh PS.

Exhibit 3 will be a copy of your CV, which was also previously marked in the previous deposition.

Exhibit 4 will be your reliance list that was also marked in the previous deposition.

Then I'm going to mark right now which is Exhibit 5, which is your invoice for your time billed to date for the POP report; is that correct?

A. Yes.

Q. Does this invoice reflect all of the time that you spent researching and writing your Prolift report?

A. There's probably some more. I have not added that up together as that's only current 'til about 12/24/2016. I sent the bill out about 1/17. So probably current 'til about 1/17. There's probably more that happened after that.

MR. BENTLEY: We'd request a copy of the later invoice if one is

submitted.

BY MR. BENTLEY:

Q. The reliance list that you attached or that you served with your Prolift report, that's the same reliance list that you submitted with your TVT report; is that correct?

A. That's correct.

Q. Did you rely upon the TVT evidence in reaching your conclusions in your Prolift report in addition to the other literature?

A. I tried to separate out a lot of the TVT literature from the prolapse literature. There may be some in my report that is overlying, but in the reports I tried to separate it out. I may not have done that a hundred percent.

Q. Looking at what's marked as Exhibit 4, which is your reliance list, how would we go back and look at which materials are the basis for your Prolift report as opposed to your TVT report?

A. Well, I have basis regarding

mesh. So those are going to be the same. Then I have basis regarding specifically mesh that is used in the Gynemesh, which is, as you know, a lighter-weight mesh than is used in the TVT mesh. So, there's general mesh and then there's specific to each product.

Q. Is that delineated in some way in your material list?

A. I think in reviewing it all, I would take it all in context that it's together, but in writing the report, I tried to separate it out.

Q. And I'm talking specifically about the reliance list, it's all combined together.

A. I understand.

Q. There's no way to split up your reliance list for your prolapse report versus your incontinence report, right?

A. I think it was -- both of -- all of it gave my gestalt for what's going on and my opinions.

Q. There's a number of internal

documents with Bates of ETH.MESH and H.MESH, for example.

Did you review all of those?

A. Yep. I may not have read everything word for word, or else we'd probably be here for years, but I did review everything.

Q. How did you decide which internal documents to review?

A. I would read the first sentence or two and see what it's pertaining to and I would decide if I should review the entire document or if I should just skim it.

Q. There's approximately seven pages of internal documents that it says you relied upon.

Is that consistent with your recollection of your review of Ethicon documents?

A. Yes.

Q. And your invoice indicates that you spent 2.0 hours reviewing Ethicon papers.

Is that the time you would have spent reviewing internal documents?

A. That would be one of them. So, that may have been not in a binder that was sent to me. I received binders and papers and papers of stuff, and I tried to review some in more depth and some in less depth.

Do I have a systematic way that I can do checkboxes for you? No, I don't.

Q. Your reliance list indicates that you reviewed a number of company deposition transcripts; is that correct?

A. Yes, I did.

Q. Did you review the entirety of those transcripts or just portions?

A. Some of it were just portions. Some of them I may have written in a little more -- I may have read a little more in depth. I don't recall which ones were more in depth than the others.

Q. Were you provided the entire transcript, or were you provided excerpts of the company depositions?

A. Some of it I was given the entire. Some of it was just excerpts.

MR. BENTLEY: Plaintiffs would request that they be provided supplemental material list indicating what was actually provided and relied upon by Dr. Winkler.

BY MR. BENTLEY:

Q. Then there's a number of depositions of the plaintiff experts.

Similarly, did you review the entire transcript for the depositions of the plaintiff's experts?

A. Some of them I had. Some of them gave multiple depositions, so I don't recall which ones I read the entirety of and which ones I read the -- sort of just skimmed them.

Q. Were you provided the entire transcripts of those depositions or just excerpts?

A. To my best of my recollection, I was provided the entire transcripts.

Q. And then you reviewed a number

of plaintiff expert reports; is that correct?

A. Yes, I did.

Q. It looks like you reviewed a number of TVT and TVT-O reports, but only two Prolift reports were plaintiffs.

Is there any reason why it seems you reviewed many more TVT reports as opposed to prolapse-related reports?

A. That was what was sent to me, so that's what I reviewed.

Q. When you were reviewing these materials, did you specifically request any further documents or reports after you started reviewing?

A. So, there were sometimes I would discuss with them and say -- and saying, This is what I've read. Do you have the full deposition? And the full deposition would be sent to me.

There were -- there was articles and literature that I actually sent over to J&J as part of my literature searches that I found that were not included in

documents that I thought may and should be included in some of their documents in the future. So, there was a back-and-forth for the last several months regarding information.

Q. And do you know any plaintiff experts outside of this litigation?

MR. BENTLEY: Let me rephrase it.

Q. Prior to your engagement in this litigation, did you know of any of plaintiff's expert witnesses?

A. So, I had heard, I did not know specifically, and I did not see it specifically, who those plaintiff experts were, but there was hearsay that certain people that we knew were expert witnesses, yes.

Q. So you knew some of these other physicians in your career, in your practice?

A. Yeah, I know some of them personally.

Q. Which ones do you know

personally?
A. Let me get to the list and I'll tell you.
Q. It's, I believe, on the last page of Exhibit 4.
A. Okay. I know Jerry Blavis. I Neerak Kohli. I know Don Ostergard, although I'm not sure if he would remember who I am. I've met Bruce Rosenzweig maybe once or twice way early in my career when I was in Chicago. Dionysios Veronikis I've met. I don't have his e-mail or anything like that. Let's see.
So, that's it from this list.
Q. Based off that testimony, the people that you've listed that you are familiar with or you know, do you have any reason to doubt their expertise or abilities in their fields?
A. I think they're all experts. I think some of them are stronger experts in certain things than other things.
Q. And they looked at the same information you did and just came to

different conclusions?
MR. ROSENBLATT: Object to form.
MR. BENTLEY: Let me rephrase it.
BY MR. BENTLEY:
Q. You don't have any criticisms of their qualifications, do you?
A. No, I do not.
Q. And you looked at their materials and the materials they looked at, right?
A. That is correct.
Q. And they, based off of their review of that information that you looked at also, they came to conclusions that are just different from your conclusions here, right?
A. I think most of their conclusions may have been based on personal experience than some of the literature that I found.
Q. Well, you've testified -- well, and let's make it clear.
We're incorporating the

deposition testimony from this morning and early afternoon from the TVT so we don't have to retread a lot of the background and general stuff.
A. Sure.
Q. But you testified earlier that your opinions today -- well, your opinions as disclosed in these reports are based upon your review of the literature in addition to your clinical practice; is that correct?
A. That's correct.
Q. Okay. And presumably, all these experts also reached opinions based off of their review of the literature and their private practice.
Would you agree with that?
A. Yeah, I would agree that they -- that's their opinions.
Q. And for whatever reason, you all have come to differing conclusions based off of both of your experience and their experience and based off of their review of the literature and your review of the

literature? You all were looking at most of the same information; you've reached different conclusions; is that correct?
A. We have reached different conclusions, that's correct.
Q. Okay. So really where I'm going is do you have any criticisms specifically of their methodology for reviewing the literature and the data to reach their conclusions specific to their methodology since you reviewed their reports?
A. I'm not familiar -- I can't comment on their methodology. I wasn't there doing the searches with them. I wasn't there reading the articles with them. So I can't comment on their methodology.
I can accept their conclusions, but I don't know how they did their searches personally.
Q. We had previously discussed what's been marked as Exhibit 3, which is your CV. I just want to go to the section on studies you've been involved in with

grants, which I believe starts on -- page 8 has your research interests.
A. Yes.
Q. We discussed a little bit you're interested in developing a model to assess various types of meshes; is that correct?
A. Yes.
Q. And those meshes, we discussed a little bit in the TVT deposition, but really the meshes that you're looking at in developing the model, those are more for pelvic floor reconstruction as opposed to the treatment of incontinence; is that correct?
A. Not necessarily.
Q. Okay.
A. It's really early stages. So we have to try to see where it goes.
Q. Okay. On the next page there's your contracts, grants and sponsor research, and you have a number of studies here.
You've done studies evaluating mesh-based repairs for prolapse, right?

A. Yes, I have.
Q. And the earliest study you have on here is an investigation titled "Non-funded safety and efficacy of sacrocolpopexy with synthetic mesh."
A. Yes.
Q. What kind of mesh would you have been investigating in that study?
A. It was likely that it was Gynemesh PS.
Q. Let's back up a little bit.
This deposition is about products that are polypropylene-based that are used to treat the indication of prolapse.
Is that fair?
A. Yes.
Q. And during your residency, did you learn about the -- did you learn about women that suffered from prolapse and how to treat that?
A. Yes.
Q. And during your residency, how were you taught, or what surgical

treatments did you learn to treat women that suffered from pelvic organ prolapse?
A. So, in residency, I was taught mostly native tissue repairs, vaginal hysterectomy, anterior and posterior colporrhaphy, as well as sacrospinous suspension and some uterosacral suspension, and I wouldn't qualify that as high uterosacrals back then. My residency was very focused on abdominal-type stuff, and vaginal prolapse repair actually was not numbers that we got in high numbers. And that was one of the reasons why I wanted to go ahead and do a fellowship and gain additional knowledge and bring that knowledge back to the New York area.
Q. And so, your residency was focused on the abdominal approach for surgery, so were you performing the abdominal sacrocolpopexy?
A. No, didn't do it. I said more abdominal-type of surgery it was focused on as opposed to prolapse surgery. If we were doing prolapse surgery in my

residency, it was vaginal hysterectomy, uterosacral suspension, anterior and posterior repair.
Q. When did you start using mesh to repair prolapse?
A. So, abdominally, I started in my fellowship. We didn't use mesh there. We used Gore-Tex. And then probably when I finished fellowship, we started using the regular Prolene mesh that we had discussed earlier this morning, and then -- and we were cutting pieces of the Prolene mesh. And then when the Gynemesh PS came out, or the Prolene Soft came out, we transitioned over to the soft version from the original Prolene mesh version.
Q. I think you just testified that you used Gore-Tex first?
A. Gore-Tex, yes. That was in fellowship.
Q. And I might have heard you wrong.
I think you said the Gore-Tex was not a mesh?

Page 26

A. It wasn't -- it was a Gore-Tex sheathe. It was a piece of sheathe. You can call it a mesh, but it wasn't the meshes that we're talking about today. Let's put it that way.
Q. It wasn't a polypropylene mesh?
A. Yes.
Q. So you started with Gore-Tex mesh, and what were the results with using Gore-Tex to treat prolapse?
A. So, Gore-Tex encapsulates, it's microporous, and there was a higher erosion -- higher exposure rate with the Gore-Tex meshes. We didn't do a lot of sacrocolpopexies in fellowship. I probably got the majority of my experience with sacrocolpopexy when I finished fellowship, actually, when I went to Maimonides and when I came over to -- to North Shore. I had extensive experience in abdominally-based surgery from my residency, but I did not have a large volume of numbers of sacrocolpopexies until then.

Page 27

Q. In approximately what time frame were you using the Gore-Tex to treat prolapse?
A. That was '96 to '98.
Q. And then from '98 -- in 1998 you began using Prolene?
A. Prolene.
Q. Do you know what construction of Prolene you were using in 1998 to treat prolapse?
A. It was the Prolene mesh that Ethicon made.
Q. Right. And you may not know, there's several iterations of Prolene mesh and sutures under the same name.
In 1998 when you were using Prolene mesh to repair prolapse, do you know one way or another which construction of Prolene mesh that was?
A. So, it wasn't the Prolene PS.
Q. Okay.
A. What they called it from before, I don't really recall. It was Prolene mesh.

Page 28

Q. Do you know that there were more than one version of Prolene mesh that Ethicon made and manufactured?
A. I was familiar with there were more than one version. I just don't remember which version. I think we tried to find a version that had the biggest pores back then.
But now we're really going back 15, 16 years.
Q. You said that Gore-Tex mesh didn't work in part because it was encapsulated?
A. Correct.
Q. And what exactly do you mean by "encapsulated"?
A. So, tissue could not grow into the mesh. Tissue can only grow around the mesh. And therefore, there was sort of a pocket that developed and went around the Gore-Tex meshes.
Q. Is that kind of like scar plating?
A. I wouldn't say it's scar

Page 29

plating. I would say there's tissue growing over it, because one of the things that happened with the Gore-Tex is that tissue didn't -- it didn't grow into it. So it was something that extruded fairly easily.
Q. When it encapsulated the mesh, did it make the tissue harder and less flexible?
A. I don't recall.
Q. Then when did you start using Prolene Soft to treat prolapse?
A. So, probably when it came out. I don't remember exactly. My understanding was Prolene Soft came out in 2002, '3.
Do you know?
Q. Did you consult on the design of Prolene Soft?
A. No, I did not.
Q. Do you recall if you did any studies on Prolene Soft to treat prolapse?
A. We didn't do any studies. Although I do think -- if it came out in

Page 30

2002, then in the study that we did, there probably were patients who got Prolene Soft, but I don't remember the exact date things came out.

Q. So you may have included patients that got Prolene Soft in a study, but you don't think you were working as a study investigator on an Ethicon-sponsored study; is that correct?

A. This was not an Ethicon-sponsored study, the one that we did in the early 2000s.

I'm trying to see if we did anything that was Ethicon sponsored.

Q. I just don't see any Ethicon activities on your CV, but based on your earlier testimony, it seems like you did some consulting for Ethicon, right?

A. So, what I did for Ethicon was preceptorships, and I think I went to one or two consulting meetings that they had beforehand that I saw from paperwork that I didn't even remember.

I did not -- so, what was

Page 31

happening was when the Gynemesh PS came out, I also implanted some of that Gynemesh PS transvaginally, and I guess they wanted to get my opinions on the transvaginal placement of the Gynemesh PS.

My partner, Dr. Lind, did more work with Gynecare, and so I don't know, can't remember what was going on back then.

Q. In your work in this litigation, Ethicon didn't provide you any information to refresh your memory about consulting work that you did with them or studies that you participated on?

A. They did. They showed me a piece of paper from 2004 where I participated in I guess one of these key opinion leader-type groups on transvaginal mesh, getting my ideas, but I did not participate in the design of the Prolift mesh.

Q. Based on the documents you reviewed in preparation for this report and in this litigation, you were shown

Page 32

documents that refreshed your memory that in 2004 you worked as a KOL for Ethicon; is that correct?

A. I went to some meeting for them that they sponsored as a, I guess, KOL.

Q. Which is a key opinion leader, right?

A. Yes.

Q. And what did those documents that you were shown show you about your opinions in 2004 regarding mesh?

A. Back then, I was also concerned about an exposure rate, that exposure can happen with the meshes. It was something that I knew and it was a concern of mine.

Q. And were you concerned with any of the design properties of the mesh as they related to the exposures?

A. So, one of the things that I had said and that I guess they had documented, that I was worried about the tanged edges causing an exposure. However, I was proven incorrect because most of the exposures are not happening at the edges,

Page 33

they're happening at the incision lines in the middle of the mesh.

Q. And those documents you may have actually referred to the edges as rough edges rather than tanged edges; is that correct?

A. I don't remember how I referred to them, and how I referred to them may not be the way that the person wrote it down.

Q. So other than some documents indicating that you were a KOL in 2004 and giving opinions regarding mesh and potential exposure, were you shown anything else to refresh your memory about your work as a consultant or participating in studies for Ethicon?

A. So, I was shown that, and I know that I was not shown monies that I received, but I know that I was a preceptor.

Q. And did Ethicon pay for you to travel and speak on behalf of the company or their products, that you remember?

Page 34

A. Yes, they did. In very few occurrences, but yes, I did get money from Ethicon for that.
Q. So, in approximately 2002 you began using Prolene Soft to do your abdominal sacrocolpopexies; is that correct?
A. Somewhere around there. Please don't pin me down to these exact dates.
Q. And once you began using Prolene Soft to do abdominal-based repairs of the prolapse, did you continue doing that procedure with that mesh for a while? Or, how did your treatment continue?
A. Yeah, I continued using that mesh for several years. I stopped using their mesh around the time I started converting from open abdominal to laparoscopic robotic.
Q. Approximately when was that?
A. 2011-ish. I wouldn't -- somewhere around there, or I started to do more volume of laparoscopic robotic somewhere around that time.

Page 35

Q. So, is it your testimony that from approximately 2002 until 2011 you used Prolene Soft consecutively as your polypropylene mesh to repair prolapse?
A. I don't know if I used it exclusively, but I predominantly used it.
Q. Did you use any other manufacturers' polypropylene meshes during that time period to repair prolapse?
A. I may have used an AMS brand. I may have used a Caldera soft mesh that they used, and I may have used something that Boston Scientific made, but the majority of my repairs back then were with the Gynemesh PS.
Q. When you say you predominantly use Gynemesh PS, does that mean that you got the sheets of Gynemesh PS and were cutting them yourself?
A. Yeah, got a sheet of mesh, cut them in half, put one of the strips on the posterior vaginal wall, one of the strips on the anterior vaginal wall and then attaching that to the sacrum, to the

Page 36

anterior longitudinal ligament on the sacrum.
Q. Probably around 2005, 2006, kits became available to treat prolapse.
Why did you continue to cut your own mesh rather than using a kit?
A. So, kits became available for a transvaginal prolapse.
Q. Right.
A. Okay. There were no kits available at that time for abdominal sacrocolpopexies, and I was trying to pick specific procedures or discussing with patients doing specific procedures based on certain clinical aspects as opposed to just switching everyone over to a transvaginal mesh.
Q. So during that time period, did you consistently do abdominal repairs, or did you also incorporate transvaginal repairs?
A. So, I did abdominal repairs, I did native tissue repairs, I did obliterative repairs is when we close down

Page 37

the vaginal, and I also did transvaginal mesh repairs, or what we know today as transvaginal mesh repairs.
Q. When did you start doing transvaginal repairs using polypropylene mesh kits?
A. So, when did I start using the Prolift kit? I got to be honest with you, I don't remember that exact date. It probably was somewhere around, I would say, 2006 or '7, but I don't remember that exact date.
Q. Did you use any other kits for transvaginal repair of prolapse?
A. So, I had been trained on the kit that came out from AMS, the Perigee and Apogee kits. I had used them, but I don't remember what volume of surgical procedures I performed with them, or particularly with any of the stuff exact numbers right now.
Q. Did you use any of the kits from Boston Scientific back in the day?
A. So, the Boston Scientific kit

Page 38

came out after the -- after the Apogee, Perigee, and Ethicon transvaginal mesh kits. And the Boston Scientific mesh kit was a little different than the Prolift kit where you were able to get apical support on a more systematic basis than you were with the anterior Prolift.
Q. Was that important for you?
A. Yeah. So, if patients had anterior and apical prolapse and they didn't have anything posteriorly, it was beneficial.
Q. What aspect of the Boston Scientific kit enabled you to get at apical support?
A. So, there was an arm that went to sacrospinous ligament, and you would attach the arm of the mesh to the sacrospinous ligament, or bring it through the sacrospinous ligament, to be more accurate.
Q. So, when the Boston Scientific kit became available, did you switch over to that kit for your main kit to do

Page 39

transvaginal repairs?
A. I don't remember the exact transition, but I may have transitioned over. The -- yeah.
Q. Because in the last deposition, we discussed that you would use a Boston Scientific sling if you were doing a Boston Scientific-based mesh repair for prolapse, right?
A. That's what I do today. I'm a little more cognizant of it because of all this litigation as opposed to mixing things up.
Q. So, when you began using the Prolift kit around 2006 or 2007, did you also use the AMS kit?
A. No, I think I was mostly using the Prolift kit.
Q. But you were trained on AMS Perigee and Apogee also?
A. Yeah, so if companies were willing to train me and I can get additional experience in the cadaver lab, I tried to take advantage of that

Page 40

situation.
Q. And were all three of these different kits available at your hospital at any given time, or is there just one brand purchased?
A. I think they were available. I can't recall exactly, but I think both of them -- either were available.
MR. ROSENBLATT: I just wanted to object to form to they weren't all available at the same time. So that's my objection.
BY MR. BENTLEY:
Q. So, when you started using transvaginal kits around 2006 after the introduction of Prolift, what percent of the woman that you treated for prolapse would you use the abdominal approach versus the transvaginal kit?
A. So, the abdominal approach we were doing much more. So, I would say abdominally we probably used on prolapse around 30 to 40 percent of the patients and kits were probably 10, maybe 15

Page 41

percent.
Q. And what would be the other percent?
A. Native tissue vaginal.
Q. By those estimates, approximately half of the cases -- approximately half of the women you were treating for prolapse once Prolift was available, once Gynemesh PS was available, approximately half of the women you were treating you were using a native tissue vaginal-based repair?
A. Very grossly. Maybe 45. Very, very grossly, gross numbers here.
Q. Did you have good results using native tissue repair?
A. Yes, I did. Yes, I still do.
Q. Because you wouldn't have recommended that and done that procedure in approximately half of the women if you were having poor results, right?
A. Correct.
Q. Do you remember when you switched -- I understand you may not have

Page 42

switched a hundred percent over, but when you would have made the switch to using the Boston Scientific kit as opposed to the Prolift kit?
A. What year?
Q. Or when.
A. I tried to go back to figure this out, to be honest with you.
Do you know when the Boston Scientific Pinnacle kit came out?
Q. I don't know.
Do you think that's approximately when you would have switched?
A. That would give me at least a reasonable base to figure it out.
I probably wouldn't have switched day one that it came out, but I may have transitioned over several months after that. And I will just also say then as part of my native tissue repairs, I consider obliterative procedures, closing the vagina down, as part of the native tissue repair.

Page 43

Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue?
A. I'd like to say somewhere around 10 percent.
Q. For obliterative?
A. Yeah, somewhere around there.
Again, these are gross estimates.
Q. So that would leave approximately 35 to 40 percent were native tissue repair?
A. Okay, yeah.
Q. And today what treatment options are you using for prolapse?
A. So, today I -- we are doing both native tissue and mesh-based repair. I do laparoscopic robotic sacrocolpopexy, I do native tissue repair with uterosacral ligaments, with fixed spinous suspension, as well as obliterative procedures, and I

Page 44

do offer --
MR. ROSENBLATT: Slow down.
A. This is an easy question for me.
MR. ROSENBLATT: You can continue your answer. I just wanted you to slow down for the court reporter.
A. And I still offer transvaginal mesh procedures to patients.
Q. When you're doing the laparoscopic, what mesh product are you using?
A. Predominantly the Boston Scientific Upsylon Y-mesh.
Q. And whether you're offering a transvaginal mesh repair for prolapse today, what mesh are you using?
A. The Boston Scientific Uphold mesh.
Q. Do you have a understanding of the mesh properties of the Upsylon Y-mesh of the pore size or weight or any of those properties?
A. Yes.

Page 45

Q. Can you describe that mesh, please?
A. It's a macroporous, quote/unquote, lightweight mesh.
Q. It's more of a newer mesh; is that correct?
A. That's correct.
Q. It's not Boston Scientific's first prolapse mesh they've introduced, right?
A. Not that I'm -- not that I'm aware of.
Q. Is it lighter than their earlier meshes?
A. I think it's -- yes, it's lighter than that.
Q. With larger pores?
A. I don't remember if it's larger pores or not. We can look at the data if we want.
Q. Does it have an absorbable component to it?
A. No, it does not.
Q. And similarly with the Uphold

Page 46

mesh, do you remember or can you tell us any of the mesh properties with that product?
A. It's also a macroporous monofilament wide pore mesh.
Q. What percent of the women you treat for prolapse today do you think you use a transvaginal-based mesh repair?
A. Less than or somewhere around maybe 5 percent, maybe less than that.
Q. What percent do you think are laparoscopic ASC?
A. Somewhere around 30, 35 percent.
Q. Then are you still doing vaginal approach native tissue repair?
A. Yeah.
Q. Can you estimate what percent?
A. Whatever the rest would be the vaginal and the obliterative.
Q. So that would be approximately 65 percent are going to be native repairs and in that 65 generally is going to be obliterative and the native tissue repair?
A. Yeah, somewhere around there.

Page 47

Q. And approximately what percent would you estimate is the obliterative?
A. Probably around 10 percent. I don't think that has changed much.
Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair?
A. That's probably about right.
Q. Do you feel that those repairs are safe and effective?
A. Yes.
Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today?
A. From what I'm aware of, yes.
(Exhibit Winkler 6, North Shore LIJ Institutional Review Board Proposal Cover Sheet, Bates No. ETH.MESH.00411090, was marked for identification, as of this date.)

Page 48

BY MR. BENTLEY:
Q. Doctor, I'm handing you what has been marked as Exhibit 6. This is a document that was produced to us with Bates 00411900.
Do you see that?
A. Mm-hm.
Q. Yes?
A. Yes, I do.
Q. And this is a North Shore Long Island Jewish Health System form.
You see that on top?
A. Yes.
Q. And that's the hospital you worked at?
A. Yes.
Q. Or you still work at, right?
A. Yes.
Q. And it's an institutional review board proposal cover sheet.
Do you see that?
A. Yes.
Q. And the study personnel is listed as Dr. Lind, Dr. Hall, and Dr.

Page 49

Winkler, yourself, right?
A. Correct.
Q. And you're listed as subinvestigator; is that correct?
A. Correct.
Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair."
Do you see that?
A. Yes, I do.
Q. And the proposed start date was November 22nd, 2002.
Do you see that?
A. Yes, I do.
I don't know how we got that proposed start date when it's -- when - I didn't sign off on this - when my partner signed off on that on March 27th, 2003. But once again, I didn't sign off on this piece of paper.
Q. Do you recall being a subinvestigator in this study regarding Gynemesh for pelvic floor repair?
A. I don't recall filling out any

Page 50

investigator paperwork on -- on this, no.
Q. So, aside from filling out the paperwork, do you remember being part of this study --
A. So, I didn't fill out this paperwork.
Q. So, that aside, noting that you didn't fill out the paperwork, do you remember participating or being a part of the study in 2002?
A. I don't remember what this study entailed and what we actually did on it in the end, if we did any work on it.
Q. It wouldn't have been unusual for you to participate in a study like this with Dr. Lind though, right?
A. No, it wouldn't have been, and he probably would have put my name on it because I was doing these procedures, as was Dr. Hall back then.
Q. When you're updating your CV in 2013, if you had been provided with paperwork indicating that you were a subinvestigator in a study to evaluate

Page 51

Gynemesh for pelvic floor repair, is that the type of information you would have liked to have added with your CV?
A. If I would have known about it, I would have added it.
This was ten years before. So, you know, either I didn't remember it or this was just a proposal and it never happened. I don't know.
Q. I'm going to hand you what's been marked as Exhibit 7.
(Exhibit Winkler 7, Monitoring Reports, Bates No. ETH.MESH.00411100 through ETH.MESH.00411113, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. This is a monitoring report with Bates 411102.
If you'll turn to the second page you can see the document is titled "Clinical Site Monitoring Visit Report."
Do you see that?
A. Yes.
Q. And it's dated March 10th, 2004

Page 52

in the top right.
Do you see that?
A. Correct.
Q. The form notes that the last visit date was December 18th, 2002.
Do you see that?
A. Let's see. Where?
Q. In the date on the top right.
A. Show me where.
Q. I think you turned the page. I'm on Bates 103. It's the second page in the document.
A. Okay.
Q. Do you see that the protocol name is "Clinical Evaluation of Gynemesh Gynemesh PS for Pelvic Floor Repair"?
A. Correct.
Q. And under the middle box it says: "Study staff present."
Do you see that?
A. Yes, I do.
Q. And you're listed again as a subinvestigator; is that correct?
A. That's correct.

Page 53

Q. And towards the bottom of the page it notes that the study's continuing and your group has entered to date 12 patients.
Do you see that?
A. That's correct.
Q. It appears on Bates 105 that someone came out to visit the site to see if the study was still going on and they signed it in 2004.
A. Okay.
Q. So based off your review of this document, does it indicate that you were at least listed as a subinvestigator in a Gynemesh PS study in 2004?
A. Yes.
Q. Does this refresh your memory at all?
A. I don't remember this independently. If I would have remembered it, I would have put it on my CV. If we did a study, I put on it.
Once again, I did this format in 2011, 2012, and this study closed in, you

Page 54

just told me, December of -- when did you tell me that it closed?
Q. I don't think we've seen that yet.
So I'm going to hand you what's being marked as Exhibit 8.
(Exhibit Winkler 8, Clinical Evaluation of Gynecare GyneMesh PS Mesh for Pelvic Floor Repair Clinical Study, was marked for identification, as of this date.)
THE WITNESS: Okay.
MR. BENTLEY: And this is another document that was produced to us. I'm not sure why the Bates is not on there. We can, for the record, submit a Bates labeled copy as needed.
And this is the Clinical Evaluation of Gynecare Gynemesh PS Mesh For Pelvic Floor Repair a Clinical Study.
BY MR. BENTLEY:
Q. Do you see that?
A. Yes, I do.

Page 55

Q. And it appears that the study was completed and results were collected and this is a summary of that study.
Is that a fair recitation --
A. That's correct, fair.
Q. I suspect you still don't remember participating in the study based off this document?
A. I don't remember.
Q. And these documents weren't provided to you in your preparation for this report in this litigation; is that correct?
A. I did not see this before today.
Q. But now seeing these, would you like to add this information to your CV?
A. Yeah, I would put information like this on my CV.
I'm not the PI, so I would never -- I wouldn't get a report on this. We don't get any reports on this, but in terms of funding and stuff, I wouldn't get any reports.
Q. And on your CV, you include

Page 56

other studies where you're not necessarily the principal investigator; is that correct?
A. Yes.
So, some of the ways that I would remember some of the stuff is I do a Pub Med search, and I don't know if this ever came up on a Pub Med search.
Q. You do a Pub Med search for yourself?
A. Yeah. Listen, I had to go back eight years.
Q. Let's put that aside and look at your report.
So, I believe we marked Exhibit 2 as your report entitled "Expert Report of Harvey Winkler MD Regarding Gynemesh and Prolift."
Is that correct, Exhibit 2 is your report?
A. Yes.
Q. And this report has a number of footnotes at the end on page 46; is that correct?

Page 57

A. Yes, it does.
Q. And there's 106 footnotes in this report; is that correct?
A. Yes, it does.
Q. And on page 41 it indicates that you signed this report on February 5th, 2017; is that correct?
A. That's correct.
Q. I think, as you testified, you may have done some work on this report subsequent to the last entries on your invoice before you submitted this report; is that fair?
A. That is fair.
Q. So, Doctor, this report you discuss a lot of literature again and have a number of citations to various findings, correct?
A. Yes.
Q. The method that you employed to find literature is you would have done keyword searches in preparation of this report; is that correct?
A. Yes.

Page 58

Q. And some of the literature you were already familiar with, correct?
A. Yes.
Q. And some of that literature was provided to by Ethicon; is that correct?
A. Correct. And then I did my own searches as well.
Q. And you also reviewed some of plaintiff's reports and their materials that they cited, correct?
A. Correct.
Q. And taking that large basket of studies and literature, again you didn't do any independent statistical analysis to somehow combine all that information into one calculation or anything, right?
A. No, I did not.
Q. So, again you're going to rely upon Level I evidence that it's a systematic review of other studies performed by the statistical experts that crunch numbers; is that fair?
A. That's fair.
Q. Okay. And so, using the Oxford

Page 59

Levels of Evidence that we've discussed today, Level I is going to be the systematic review and that's the highest level of evidence, correct?
A. Correct.
Q. And we've previously discussed some of the Cochrane reviews, and I think you said that you would a hundred percent rely on those.
Is that fair regarding your Prolift report also?
MR. ROSENBLATT: Object to form.
A. I don't know if I hundred percent rely on one particular study. I try to take them all in context.
Q. So, you would definitely put the Cochrane reviews as the highest level of evidence in this situation also?
A. It's one of the types of the highest levels, yes.
Q. And is there any reason you wouldn't a hundred percent rely on the Cochrane review as you sit here today that you can tell us?

Page 60

MR. ROSENBLATT: Object to form; mischaracterization.
I think he said primarily, not a hundred percent.
MR. BENTLEY: I wrote down a hundred percent.
BY MR. BENTLEY:
Q. But regardless, is there any reason today why you wouldn't a hundred percent rely on the Cochrane review in regarding the mesh repairs for prolapse?
A. That's not the only thing that I would rely on a hundred percent.
Q. I see what you're saying.
The 2016 Maher Cochrane review, do you have any criticism of that study as you sit here today?
A. I don't -- I'd like to see the study before I criticize it.
Q. If you had any criticisms of that study, would they be included in your report?
A. Not necessarily.
Q. So, does your report contain a

Page 61

true and accurate list of all of your opinions you intend to offer at trial for the jury regarding the Prolift and the Gynemesh PS?
A. It does, but if I remember correctly, even in my report, I reserve the right to modify opinions as I learn stuff.
Q. As new evidence becomes available?
A. As new evidence becomes available, thank you.
Q. And the 2016 Maher report was available when you wrote this report, right?
A. Yes.
MR. ROSENBLATT: And there are several Maher 2016 Cochrane reviews. So I just want to make sure you're referring to vaginal prolapse as opposed to apical repair. Just because there are multiple ones, I want to make sure you guys are talking about the same one.

Page 62

(Exhibit Winkler 9, Maher Cochrane review, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. Doctor, I'm handing you what is marked as Exhibit 9, which is a Cochrane review entitled "Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse."
Do you see that?
A. Okay. Yes, I have it.
Q. And we were discussing the Cochrane reviews are a Level I evidence, right?
A. Yes.
Q. And I was asking as you sit here today, do you have any criticisms or reasons to not rely upon the latest Cochrane review regarding Prolift and mesh-based repairs for prolapse?
A. Once again, I don't rely on just one study for an opinion whether or not to do and use a surgical procedure and a device.

Page 63

Q. So other than the fact that you don't rely upon one study, do you have any other reasons not to rely upon this study or criticisms of this study?
MR. ROSENBLATT: Object to form.
If you want to skim through it or ask if he has any criticisms about a particular section, that might be easier, but that's just very broad.
BY MR. BENTLEY:
Q. Well, first, Doctor, do you understand the question?
A. Do I have any criticisms of the study?
Q. Yes.
A. Is the question.
Overall, I accept its findings. I have not reviewed part-by-part every single methodology that they have performed.
Q. Okay. Do you have any -- do you know of any studies that they didn't included in their analysis that they should have?

Page 64

A. Well, I'd have to go over their search methods and review it. I'm not -- so, I -- and I haven't done that.
MR. BENTLEY: Let me rephrase it.
BY MR. BENTLEY:
Q. In your report, you don't identify any problems with the Cochrane 2016 review such that they failed to include some studies that you think they should have included?
A. I did not include that in my report. However, it's possible that they missed some studies or should have included some studies.
Q. And in your report, similarly you don't identify any methodological criticisms with the Cochrane 2016 review performed, with their meta-analysis combining several RCTs and generating various complication rates? You don't have any criticisms of the methodology they employed to make their meta-analysis, do you?

Page 65

A. Currently, I don't have any criticisms.
Q. And you didn't disclose any in your report, right?
A. I did not disclose any in my report.
Q. You would agree that the 2016 Cochrane review is one of the most powerful and reliable sources of data available?
A. I think it's one of the reliable sources available. I guess most powerful is subjective.
Q. And by powerful, I mean they have reviewed expansive number of studies, had a preset inclusion/exclusion criteria, had a preset methodological analysis and performed meta-analysis to combine those studies.
Is that fair?
A. Fair enough.
Q. And that's what constitutes Level I evidence, is someone that undertakes that type of statistical

Page 66

analysis?
A. Fair enough.
MR. ROSENBLATT: Greg, we've been going about an hour. I don't want to cut you off.
MR. BENTLEY: It's good. We can take a break.
(Recess taken from 5:09 p.m. to 5:17 p.m.)
BY MR. BENTLEY:
Q. All right, Doctor. We are back from a break.
Are you ready?
A. Yeah.
Q. We were discussing the 2016 Cochrane review from Maher regarding transvaginal mesh for prolapse repair.
Do you remember that?
A. Yes.
Q. And we just entered that review as an exhibit, I think it's Exhibit 9; is that correct?
A. That is correct.
Q. You discussed this review in

Page 67

your report several places.
If you turn to page 20 in your report, I believe it's the first time you mention this review.
A. Okay.
Q. And at the bottom of page 20 you note that this is the most recent review, and it shows good objective and subjective outcomes at one to three year for mesh.
Is that correct?
A. That's correct.
Q. And on the next page you discuss some more findings from the Cochrane review.
A. Yes.
Q. Turning back to the Cochrane review, which is Exhibit 9.
On page 1 of the review is the abstract which is a condensed version of the study and its findings; is that fair?
A. That's fair.
Q. And the authors ultimately conclude on page 2 that: "While transvaginal permanent mesh is associated

Page 68

with lower rates of awareness of prolapse, reoperation for prolapse and prolapse on examination than native tissue repair is also associated with higher rates of reoperation for prolapse, stress urinary incontinence, or mesh exposure and higher rates of bladder injury at surgery and de novo stress urinary incontinence."
Do you see that?
A. I got to be honest with you, no.
Q. We're on page 2 under "Author Conclusions."
A. Okay.
Q. And my question is that first conclusion, you don't discuss that conclusion in your report; is that correct?
A. That's not true, I think.
MR. ROSENBLATT: Take as much time as you need to look through your report.
(Pause.)
BY MR. BENTLEY:
Q. So, on page 20 and 21, you don't

Page 69

mention those conclusions; is that correct?
A. I'm looking, sorry.
Q. That's fine.
A. Really.
(Pause.)
A. So, I did note that there were recurrence -- the recurrence and rates of repeat surgery for prolapse were both lower in the mesh group and then although more women in the mesh group required repeat surgery for the combined outcome of prolapse stress incontinence and mesh exposure.
Q. I apologize, actually.
Let's look at the second conclusion. The Cochrane 2016 review authors conclude that: "The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery."
Do you see that in the Cochrane review?
A. I see that, yes.
Q. And that conclusion, do you

Page 70

agree with that conclusion?
A. I think that depends on the patient, and I understand when you're doing it on thousands of patients and younger patients that it may not be the first type of repair that you're doing, but it may be a primary repair in certain types of patients. So basically it's saying is that you shouldn't do a transvaginal mesh repair in everybody, especially in patients in primary surgeries, and I've always agreed with that.
Q. So you would agree that there's limited utility for the transvaginal mesh in primary surgery for repair of prolapse?
A. I think the word "limited" is a tough answer to -- question to answer.
So, I think in the patient who's 80 years old with a prolapse surgery and who's not sexually active and wants a minimally invasive procedure, it may have very good utility in those patients.
I understand what you're trying

Page 71

to say in limited utility in sort of everybody, but there are patients that transvaginal mesh is appropriate for, in my opinion, and there are patients that it may not be appropriate for, in my opinion.
Q. So let's narrow that down.
You would agree that transvaginal mesh repairs for prolapse are not right for everyone, right?
A. They're not the right surgery for everyone.
Q. There's a limited group of people where that's the appropriate -- in your opinion, where that's the appropriate surgery to treat prolapse; is that correct?
A. In my opinion, yes, there's a certain patient population that may -- where transvaginal mesh may be more or less appropriate.
Q. And it's not appropriate for the general population of women that suffer from prolapse; is that correct?
A. That depends on the patient's

Page 72

goals and expectations from the surgical procedure. And I think that's what it's pertaining to, in my opinion.
Q. The authors continue in the Cochrane review: "While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there's currently no evidence to support this deposition."
Do you see that?
A. Page 2?
Q. Yes, the last sentence of that paragraph in the conclusion.
A. Based on this review, I will agree.
However, once again, in specific patients who have recurrence, and if you look at the ACOG guidelines, the ACOG has guidelines that mesh may be, and if we can pull them out that would be even better, may be appropriate for patients with recurrence.
Q. For limited patients that are suffering from recurrence, transvaginal

Page 73

mesh may be appropriate in that situation.
Is that consistent --
A. Repeat that again?
Q. Transvaginal mesh may be appropriate for patients that suffer from recurrence, that may be the appropriate treatment for prolapse in that situation; is that correct?
A. It may be for them, and there are some patients who it may be a primary repair appropriate for them, depending on that specific patient.
Q. Okay. In the Cochrane review here is saying that currently there's no evidence to support this position.
A. No, they're saying there's limited utility as used in primary surgery.
Q. In the last paragraph they state: While -- I'm sorry, in that first paragraph, last sentence, the authors of the Cochrane review conclude: "While it is possible that women with higher risk of recurrence, the benefits may outweigh the

Page 74

risk."
And that's the subgroup that you're talking about where Prolift and Gynemesh PS is the appropriate repair, right?
A. It could be an appropriate repair in one of those patient populations.
Q. And the Cochrane review looked at that and concluded there's currently no evidence to support this position. That's their conclusion, right?
A. But they're also saying it may be possible then that the benefits may outweigh the risks.
Q. There's a possibility, but there's currently no evidence to support that; is that correct?
A. There's no evidence that the Cochrane review looked through -- I'm trying to remember if there was a paper that specifically looked at recurrence. I think there was.
Q. Well, I'm sure counsel will

Page 75

bring that up if we have that.
A. Okay.
Q. But staying on the Cochrane review, which is the Level I evidence, the highest level of evidence, right?
A. Correct.
Q. And these authors looked at a lot of studies. We can look at the methods, and we will.
And based off of their review, they concluded that there's no evidence to even support that limited possibility; is that correct?
A. They accepted that it's possible, but they did not find any evidence to support it, correct.
Q. Ultimately they decided that the risk-benefit profile means transvaginal mesh has limited utility in primary surgery.
And is that consistent with your opinion here?
A. Overall, I would say that, but on a patient-specific type of discussion,

Page 76

I don't know if I could say that for each particular type of patient. If a patient has a primary prolapse with a bad history of intra-abdominal adhesions, bowel obstructions or many reasons why I wouldn't want to go and place an abdominal mesh, that may be an appropriate patient for a transvaginal mesh.
Q. So generally you would agree that the risk-benefit profile means that transvaginal mesh like Prolift and Gynemesh PS has limited utility in primary surgery, but there may be exceptions based on an individual patient where it's appropriate and not exception; is that correct?
A. Yeah, there are certain patients where I do not believe it has limited benefit and there are major benefits.
And can I comment that's why 522 studies are being performed today to decide whether or not there is a benefit or not.
Q. It's your testimony that

Page 77

Ethicon's performing 522 studies today on Prolift or Gynemesh PS for prolapse?
A. Nope, it's not my -- it's not my testimony at all.
My testimony is that there are 522 studies being performed to ascertain whether or not transvaginal mesh is an acceptable form of treatment in patients with -- for patients with primary surgery.
Q. That's happening today for Ethicon products?
A. Once again, I said it's not for Ethicon products, but for transvaginal mesh. The Cochrane review is not only for Ethicon products. It's on all polypropylene meshes that are placed transvaginally.
Q. On the previous page under the main results of the abstract, do you see a section, Doctor?
A. Previous page, page 1?
Q. Yes.
A. Yes, I do.
Q. They note under "Main Results"

Page 78

that they included 37 RCTs.
Do you see that?
A. Yes.
Q. That's a fairly large number of randomized control trials to include, would you agree?
A. I would agree that's a good number.
Q. Would you agree that that provides a powerful basis or statistical basis that's a powerful number of studies to include?
A. I think it's a good number. I don't know if I would use the word "powerful," but I think it's an adequate number.
Q. Do you have any understanding how many RCTs you used in your analysis?
A. I didn't count up the number of RCTs.
Q. Turning back to page 2, there's some summaries of their findings. I want to draw your attention to the last paragraph.

Page 79

Do you see it starts with "Permanent mesh"? Are you with me?
A. Yes.
Q. And Maher writes: "Permanent mesh was associated with higher rates of de novo stress incontinence."
Do you see that?
A. Yes, I do.
Q. And it also notes that there's a higher rate of bladder injury.
Do you see that?
A. Yes, I do.
Q. And do you agree with those findings, that permanent mesh is associated with a higher rate of de novo stress incontinence and bladder injury?
A. I agree that that's what has been seen with these procedures, yes.
Q. Is that consistent with your opinions in your report?
A. Yeah, I think I wrote that in my report.
Q. Doctor, earlier in the earlier deposition today we were discussing your

Page 80

opinion as to what acceptable rates of complications were.
Do you remember?
A. Yes, I do.
Q. And similarly, here in your report you cite a number of different studies with a fairly wide variation in different findings, and I have some questions.
As you sit here today, based on your review of the literature and your clinical experience, do you have an estimate or an opinion as to what an acceptable rate of mesh exposure is on prolapse repairs using mesh?
MR. ROSENBLATT: Object to form.
BY MR. BENTLEY:
Q. That are transvaginally placed?
A. My -- in my experience, what I would think is going to occur in our patient population is that somewhere around a 10 to 12 percent mesh exposure rate is going to occur with a transvaginal mesh.

Page 81

Q. And that wasn't really my question.
What's an acceptable rate of exposure for transvaginal mesh repairs to treat prolapse, in your opinion based off of your review and your clinical experience?
A. So, my expected rate is my acceptable rate.
Q. And so something, an exposure rate higher than 12 percent would cause you concern?
A. Not necessarily. It depends on what the exposure is and how symptomatic it is and what we're doing for that exposure.
Q. Doctor, would you please turn your attention to page 16 of the 2016 Cochrane review we were looking at?
A. Okay.
Q. On the left-hand column it says: "1.2.3. Surgery for prolapse stress urinary incontinence or mesh exposure."
Do you see that?

Page 82

A. I do.
Q. The authors began: "Women who had a transvaginal mesh repair were more likely to undergo repeat surgery for prolapse stress urinary incontinence or mesh exposure than those undergoing native tissue repair."
Do you see that?
A. I see that.
Q. And you agree with that finding, is that correct, that that's what this shows?
A. I agree that's what they wrote, yeah.
Q. And as we discussed, you don't have any methodological concerns with the Maher study, correct?
A. Offhand, I do not.
Q. And in your report, you don't disclose any criticism of the study, right?
A. I did criticize one thing. Let me just check.
(Pause.)

Page 83

A. So, what I criticize in the study on exposure and reoperation rate is that the way we managed an exposure in the -- in our early experience with transvaginal mesh has changed dramatically how we manage an exposure today.
So, initially when we were -- when I was and other people were implanting these meshes, any time we saw an exposure, we thought that needed to be treated. We subsequently learned that some of these exposures, and many of these exposures are asymptomatic, and if you have an asymptomatic exposure, you do not have to treat that.
The Cochrane review is basing some of that reoperation and a lot of these studies are basing their reoperation rates on the earlier way we managed meshes, transvaginal mesh exposures.
Q. And you wouldn't want to subject a woman to an additional surgery unnecessarily, right, to repair an exposure? Is what you're saying?

Page 84

A. Well, that's what I'm saying. So once again, if she's asymptomatic, we subsequently learned that these asymptomatic mesh exposures are of minimal risk to the patient and we can observe and watch them as opposed to taking the patient back to the operating room.
Q. Because you don't want to subject the woman to a second surgery unless you absolutely have to, right?
A. We wouldn't want to do surgery that is unnecessary.
Q. Because each subsequent surgery has increased risks attendant to it, right?
A. I think every surgery has risk. I don't know if you want to say each subsequent surgery has more risk.
Q. Well, each time you're doing pelvic surgery --
A. Any time you do surgery, there's risk associated with it.
Q. And each time you do pelvic surgery, you're potentially creating more

Page 85

scar tissue in the pelvis which complicates further surgeries; is that fair?
A. I can agree with that. Fair enough.
Q. So if you can avoid it, you don't want to perform extra surgeries on women; is that correct?
A. It's correct.
Q. On page 16 of the Cochrane review on the right-hand column there's a Section 1.4.2 Mesh Exposure.
Do you see that?
A. Yes.
Q. And they provide a finding from their analysis of 19 RCTs and they state: "Anterior repair only. Mesh exposure was reported in 10 percent women after anterior permanent mesh repair."
Do you see that, the first bullet?
A. Yes, I do see that.
Q. And the second bullet is: "Multicompartment repair. Mesh exposure

Page 86

was reported in 17 percent after multicompartment repair."
A. I see that too.
Q. And 17 percent is almost 50 percent higher than your 12 percent acceptable rate; is that fair?
A. No, it's not fair. They're putting in two pieces of mesh here. There's an anterior and a posterior piece of mesh. So you're going to get a cumulative result from both those pieces.
Q. Is it fairly common to do an anterior and posterior repair statement?
A. I can't respond in how fairly common it is. Depends on what was going on with the patient.
Q. So, your acceptable exposure rate is dependent upon whether it's anterior or posterior repair or a combined repair?
A. So, my acceptable exposure rate, if you're going to do total exposure rate, is going to be increased if you put in an anterior and posterior piece. So 10 to 12

Page 87

percent for an anterior, 10 to 12 percent for a posterior.
Q. So ultimately, do you think that the true exposure rate if you're talking about anterior and posterior repair with the Prolift or Gynemesh PS is 17 percent?
MR. ROSENBLATT: Object to form.
A. Say that again.
Q. How about what's your opinion as to the actual exposure rate when you do an anterior and posterior repair with mesh transvaginally?
A. If I do both?
Q. Right.
A. If I'm doing an anterior and posterior, I think you can see up to a 20 to 24 percent exposure rate because you're putting in two pieces of mesh. So 10 to 12 percent anterior, 10 to 12 percent posteriorly. If I remember my statistics, you add them up and you get 20 to 24.
Q. Do you agree with the Cochrane review that found that women undergoing a transvaginal permanent mesh repair were

Page 88

more likely to have a bladder injury than those with the native tissue repair?
A. I'm going to say it depends on how you're doing the procedure, who's doing the procedure, but that's what their data shows and I will believe that.
Q. And in part, that's why you think that the Prolift and Gynemesh PS repairs are not necessarily the primary surgical intervention for women suffering from prolapse; it's more of a select group maybe with higher recurrence? Is that fair?
A. I think the patients you put transvaginal mesh in need appropriate counseling and discussion of putting in the transvaginal mesh. There may be patients who receive more benefit from a transvaginal mesh than others?
Q. But the risk-benefit profile isn't necessarily appropriate for all women when you're doing a prolapse repair; is that correct?
A. I would mention this to all

Page 89

woman, but depending on what their goals are. I mean, I mention that there's transvaginal mesh to every single patient that comes in for a prolapse. Based on their goals, their age, their history, their sexual function, the risks of a transvaginal mesh are not worth it to those patients. I'll agree to that.
Q. Do you agree that the Cochrane review's conclusion is that permanent mesh like Prolift and Gynemesh PS implanted vaginally has increased morbidity?
A. Where do you see that?
Q. On page 29 under "Author's Conclusions."
A. Page 29?
Q. Yes.
Generally do you agree with this conclusion that permanent mesh is associated with increased morbidity?
A. If you include mesh exposure, yes. Other than that, other complications seem to be on par with the native tissue.
Q. We've been talking about

Page 90

exposure.
With regard to the complication of dyspareunia, do you have an opinion as to whether transvaginal mesh may increase that risk as compared to native tissue repairs?
A. Transvaginal mesh is comparable to native tissue repairs for dyspareunia.
Q. Could you please turn to page 30 of your report? You see your paragraph where you begin "There's no doubting," on page 30?
I'm sorry, you're on --
A. Yeah, yeah, I want to find something in the Cochrane review as well since we've been discussing it.
(Pause.)
Q. In the second line in that paragraph, you say: "Intuitively we may even reason that transvaginal mesh procedure may increase this risk." Talking about dyspareunia.
Why intuitively would you reason that the mesh procedures would increase

Page 91

dyspareunia?
A. 'Cause I'm putting in a foreign body into the anterior vaginal wall, and the foreign body, any time we do anything extra, there may be an increased risk for developing complications.
However, the data does not substantiate that there's an increased complication of dyspareunia with transvaginal mesh.
And I think the Cochrane review also comments on dyspareunia, and the Cochrane review on page 17 going to 18: "There was no evidence of a difference between the groups in the rate of de novo dyspareunia."
Q. And my question is why in your report do you state that intuitively the transvaginal mesh may increase the risk of dyspareunia?
MR. ROSENBLATT: Object to form; asked and answered.
A. Once again, intuitively, if we're putting in a foreign body, if we're

Page 92

doing any extra surgery, you may think hey, this can cause more problems.
However, the data does not support that.
Q. You're comparing Prolift and Gynemesh PS to native tissue repair on page 30.
Do you see that? You state that: "Native tissue repairs, as well as transvaginal mesh procedures like Prolift and Gynemesh PS, can cause dyspareunia."
A. Yes.
Q. Then you state: "Intuitively we may even reason that a transvaginal mesh procedure may increase this risk."
So the native tissue repair, that's going to be a foreign body that's implanted transvaginally, correct?
A. Yes.
Q. But you're implanting the mesh and you're saying the mesh is going to increase this risk as compared to the native tissue repair, which is also a foreign body implanted transvaginally.

Page 93

I'm just trying to understand why intuitively you would reason that the mesh is going to increase that risk?
A. So, some people may think that, and when we started putting in meshes we actually counseled people that we may have a higher dyspareunia rate with transvaginal mesh. However, once again, the data does not support there's an increased rate of dyspareunia with transvaginal mesh as compared to native tissue in multiple studies.
Q. I'm trying to figure out why you wrote this in your report.
Why would you reason that the transvaginal mesh increases the risk of dyspareunia as compared to native tissue repair?
A. I didn't say it increases the risk of dyspareunia. I said that you may think it increases the risk of dyspareunia, but the literature has proven that it doesn't increase the risk.
Q. So you don't reason that the

Page 94

transvaginal mesh procedure would increase the risk?
A. The data does not support that transvaginal mesh increases the risk of dyspareunia.
Q. Doctor, do you have an estimate as to what you, based on your review of the literature and clinical experience, as to what the de novo dyspareunia rate is after transvaginal mesh is implanted for prolapse?
A. That's not a number that I have off the top of my head, but it's something that I included in my report. So let's -- we're talking about transvaginal mesh or we're talking about abdominal mesh now?
Q. Prolift and Gynemesh PS implanted transvaginally.
A. Sure, let's go to that.
(Pause.)
A. So, different studies have reported different numbers. Native tissue repair by Abramov in 2005 showed an increase in dyspareunia from increase from

Page 95

8 percent to 17 percent.
Let's go to transvaginal mesh.
(Pause.)
A. I know Nieminen actually showed a dyspareunia rate lower in the mesh group. Native tissue had a 13 percent reported evidence of vagina too tight and 8 percent in the mesh group.
Carey in 2009 did a 12-month follow-up of dyspareunia, showed 16.7 percent of sexually active in women in the mesh group and 50.2 percent in the no mesh group developed dyspareunia. So we're going to see about a 15 percent, once again gross number, of dyspareunia rate after our surgical procedures.
Q. So, I'm trying to figure out what you intend to testify as to these complication rates.
So, other than just reciting findings from four or five different studies, do you have any type of number that you're going to tell the jury as to what the de novo dyspareunia rate is after

Page 96

transvaginal mesh for prolapse repair?
A. My answer is going to be it's similar to native tissue repairs.
Q. And that's based upon just discussing a lot of findings with no statistical analysis; is that correct?
MR. ROSENBLATT: Object to form. He has an entire report here, so he's not going to limit his answer to the question.
BY MR. BENTLEY:
Q. You can answer, please.
A. So, what's the question again?
Q. Other than just citing a bunch of studies and then coming up with some estimate, I'm trying to figure out what methodology you employed to get to this estimate?
A. So, this is my what I used and then I'm going to go to the 3systemic reviews that show that there's no difference in dyspareunia rates for native tissue repairs and transvaginal mesh repairs.

Page 97

Q. So, ultimately you're going to be saying that the rate is whatever's in the systematic review?
MR. ROSENBLATT: Object to form.
BY MR. BENTLEY:
Q. Is that correct?
A. I am going to say the rate is going to be a composite of the systematic reviews.
Q. And what's the composite rate going to be that you're going to testify to to the jury?
A. I'm going to testify, like I said, it's out there and I will -- if you are going to pin me down that I have to answer a number, which I got to tell you right now I'm not comfortable with, it's going to be somewhere in the 15 percent range, 10 to 15 percent range.
Q. So, if a study found de novo dyspareunia after mesh repair higher than the 10 to 15 percent range, would that cause you concern?
MR. ROSENBLATT: Object to form.

Page 98

A. I'm sure we're going to find studies that are higher and we're going to find studies that are lower.
Q. And so you just picked the middle ground, or how did you reach that 10 to 15 percent range?
A. So, I'm trying to pick a middle number, yeah.
I told you I wasn't comfortable with giving you a number.
(Exhibit Winkler 10, Dietz article, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. Doctor, I'm handing you what's been marked as Exhibit 10. This is a study by Viviane Dietz and Christopher Maher.
Do you see that?
A. Yes, I do.
Q. And this is actually the same Christopher Maher that is the lead author on the 2016 Cochrane.
Do you see that?

Page 99

A. Yes, I do.
Q. And this study is titled "Pelvic organ prolapse and sexual function."
Is that correct?
A. Yes, it is.
Q. It was published in 2013 in the International Urogynecological Journal, correct?
A. Correct.
MR. ROSENBLATT: It's reference number 30 in his report.
MR. BENTLEY: What page is it?
MR. ROSENBLATT: Page 29.
THE WITNESS: I have it on page 21.
MS. THOMPSON: It's 21 and 29 and 30.
BY MR. BENTLEY:
Q. So, I believe you just testified that the true range that you believe for de novo dyspareunia after transvaginal mesh repair for prolapse is 10 to 15 percent; is that correct?
A. You asked me to pick a number

Page 100

out of a hat, and that's what I did.
Q. I'm not asking you to pick a number out of a hat. I'm trying to figure out what you're going to tell the jury is the actual rate of dyspareunia after transvaginal mesh.
MR. ROSENBLATT: Object to form; asked and answered. I think he's told you it's going to be similar, but that an average would be 10 to 15 percent or will be some studies that are higher and some that are lower.
BY MR. BENTLEY:
Q. So, what methodological analysis are you doing on the statistics to reach a 10 to 15 percent number?
A. I'm not. You're just asking me right now for a number to give you a number and you won't let me go on without giving you a number. So I have to give you something.
Q. Well, your report you cite a lot of studies; is that correct?
A. Right. So you can't -- that's

Page 101

why I'm saying I can't be pinned down to a number.
Q. And you provided a large number of different findings; is that correct?
A. Yes, the numbers depend on your patient population. The numbers depend on your -- there's a lot of variables that go into sexual dysfunction or pain with intercourse, and what I'm prepared to testify is that, and I will tell the jury that I -- it's very hard to come down to an exact number of what patients are going to get dyspareunia and pelvic pain with each particular type of surgery. I wish I knew that. Then I can --
Q. So you're not going to --
A. It's a range.
Q. -- provide a complication rate for dyspareunia, is that your testimony?
MR. ROSENBLATT: Object to form. If he's asked about a particular study, then he's going to comment on that study.
MR. BENTLEY: The jury's

Page 102

entirely capable of reading a study.
I'm trying to figure out what expert analysis he's going to bring to the jury.
MR. ROSENBLATT: The jury can read a study all by themselves?
MR. BENTLEY: Well, I mean, if you're just going to regurgitate findings, that's entirely not an expert analysis. You know that.
MR. ROSENBLATT: No, he's providing his opinions based on all of the studies --
MR. BENTLEY: I'm trying to figure out what his opinion is.
MR. ROSENBLATT: I know. And I'm not trying to be disruptive. I'm just saying he has cited studies that cite specific rates, but you're not asking him what is that range that's reported in the studies. You're just asking him --
BY MR. BENTLEY:
Q. I'm saying based upon your

Page 103

review of the literature as cited in the report, what is the true range of de novo dyspareunia that you intend to testify to at trial?
A. Once again, I intend to testify that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number.
Q. So you don't know -- let's break that down.
You don't have an opinion as to the true rate of native tissue repair for de novo dyspareunia; is that correct?
MR. ROSENBLATT: Object to form; mischaracterization.
To the extent he's relying on particular studies, he will discuss those opinions, but to the extent you're asking him to pin it down to a specific number, he's saying that's difficult to do.
MR. BENTLEY: Counsel, can we minimize the speaking objections? If

Page 104

you have an objection to form, I appreciate that.
BY MR. BENTLEY:
Q. Doctor, do you intend to offer an opinion at trial as to what the true complication rate is for de novo dyspareunia after a native tissue repair?
A. In the literature, if I didn't do the full systemic review and go through every single number that I have here, I would probably say that there is somewhere in the range of a 10 to 15 percent rate.
In my hands, do I believe that it is lower? Yes, I do. However, I have not done like a systematic review, but I have followed up on my patients and followed my native tissue repair patients, and I try to pick the appropriate surgery with the patient to try to minimize some of these risks of native tissue dyspareunia rates.
Q. Okay. And so it's your estimate and your opinion that you intend to testify to that the range is approximately

Page 105

10 to 15 percent for native tissue repair, correct?
A. Yes. And that also depends on what kind of repair that you're doing. If you're doing a posterior repair, if you're doing an anterior repair, but if we're going to lump everything together, I think we can come to that number.
MR. ROSENBLATT: Maybe I can help streamline this. I don't think he's offered in his report a specific number. But if you're going to ask him --
MR. BENTLEY: Well, if we're just going to say it's about the same as something else, I'm entitled to know what he's comparing it to and how he reached that. We haven't figured out any methodology for doing any type of combination of these studies.
A. So, I look at the Cochrane review, its the Schimpf review, the meta-analysis that are high-level data to come to my conclusions.

Page 106

Q. Doctor, what's your opinion as to the complication rate of chronic pain after a native tissue repair done transvaginally for prolapse?
A. The chronic pelvic pain rate, are you including dyspareunia in that or not including dyspareunia in that?
Q. You can tell me both, if that's easier.
A. I would think I would like to just exclude dyspareunia. Let's assume they're not.
I also think it's low. I think the chronic pain rate from a native tissue repair depend -- is going to be in the low numbers, the low single digit numbers.
Q. And then your opinion is the transvaginal mesh used to treat prolapse is going to be approximately the same as native tissue repair; is that correct?
A. That's what's in the studies. And on chronic pain it's very limited data, if I'm correct.
Q. So, when you say a very low

Page 107

number, what numerically are we talking about in a range?
A. Range anywhere between, if I have to pick a number, once again which I --
Q. Based upon your review of the literature and your systematic reviews.
A. So let's go through the numbers here. I wasn't prepared to give a number like that.
Q. Well, let's be clear.
You're establishing that Prolift and Gynemesh PS are safe because you think they're safe as native tissue repair; is that fair?
A. Based on the literature I reviewed, there's no increase in rate of dyspareunia rates and chronic pain rates.
Q. Right. So saying there's no increase in one rate as compared to the other one, I have no idea what rates you're comparing. It's not -- I'm not trying to belabor this, but --
A. I wish studies would give a rate

Page 108

exactly. That would make all of our lives easier, but it's a variable rate and takes into account multiple factors, and that's why we don't have that specific rate that you're asking for.
Q. Maybe let's do it this direction.
Which studies -- you have 40 pages of studies in here. Which studies do you find provide better evidence as to other ones? Did you give some of the studies higher deference than other studies?
A. So, the Cochrane review which we just discussed had a higher deference. There was a recent -- let me see. Let's go back here.
(Pause.)
There's the Withagen study, the Altman study.
Q. Let's do those one by one.
Is the Withagen study a systematic review meta-analysis?
A. No, it's not.

Page 109

Q. And is the Altman review a systematic meta-analysis?
A. No, it's not.
Q. What other studies did you find most compelling?
A. So, the only systemic review that I included in my report was the Cochrane review.
Q. And the Cochrane review, as we've seen, the authors concluded that the risk-benefit profile doesn't make sense for a primary treatment surgery for prolapse, right?
MR. ROSENBLATT: Object to form.
A. But they also showed that there was no difference in dyspareunia and pelvic pain.
Q. Right.
A. Associated with the two repairs.
Q. So your conclusions are just different?
A. No, we're concluding the same thing.
Q. Maybe I missed it.

Page 110

So you do agree that the risk-benefit profile for Prolift and Gynemesh PS that it doesn't make sense as a primary surgery for general population with the exception of some -- the exception of the possibility that some high risk patients it might make sense for. Do you agree with that?

A. In my opinion, transvaginal mesh is not the procedure that patients will choose based on their goals.

How's that?

Q. Would you agree with --

MR. ROSENBLATT: Object to form.

Could you read back that answer?

(The requested portion of the record was read by the Court Reporter.)

A. That patients may choose.

Q. So the patients are choosing not to use a transvaginal mesh as the primary treatment for their goals?

A. They may choose that, yes.

So, if I'm putting a synthetic in and a patient wants a synthetic

Page 111

procedure, they may choose to go with an abdominal sacrocolpopexy as opposed to a transvaginal mesh, understanding that the sacrocolpopexy has increased risks of it being an intra-abdominal procedure, but abdominal sacrocolpopexy has a lower risk profile likely for dyspareunia.

Q. Let's go at this way.

Today you do approximately -- today for approximately 5 percent of the patients you treat for prolapse, for 5 percent of them you're doing a transvaginal mesh repair?

A. Yeah, at the most, yeah.

Q. And that's consistent with your understanding of the risk-benefit profile of these devices; is that fair?

A. For the patients that I'm treating, that's fair.

Q. So maybe the mesh repair transvaginally is appropriate in maybe 5 percent of the patients consistent with your clinical practice?

A. That I didn't say. That's maybe

Page 112

5 percent of my patients are choosing that.

I will say most patients at this point in time are scared away from transvaginal mesh and won't even entertain the thought of transvaginal mesh because of the advertisements and ongoing litigation that's out there, and every single patient almost brings it up.

Q. Well, how about what percent of your patients that you treat for prolapse do you think Prolift and Gynemesh PS is appropriate for?

A. I think it could be an appropriate procedure for a larger percentage as long as they understand the risk and the benefits. But we're not even getting there at this point in time, and I understand that, and I never push a patient into a procedure, especially if they don't want it. That's not the right thing to do. But I think that the conversation is even stopping because of what's going on.

Page 113

Q. Doctor, you cite to a number of transvaginal mesh studies in your report, and then you cite to some studies and you provide findings specifically for Prolift and Gynemesh PS.

My question is are you relying upon other mesh products to reach your opinions regarding the safety and efficacy of these Ethicon products?

A. Other mesh products will be in there, but the -- the predominance of data is on Ethicon products.

(Exhibit Winkler 11, Altman article, was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. Doctor, I'm handing you what's being marked as Exhibit 11, which is the Altman study we discussed.

A. Yes.

Q. And you're familiar with the Altman study?

A. Yes.

Q. And the Altman study was

Page 114

published in the New England Journal of Medicine; is that correct?
A. That's correct.
Q. That's a reputable publication, right?
A. Yes.
Q. And the article is titled "Anterior Colporrhaphy Versus Transvaginal Mesh For Pelvic Organ Prolapse."
Is that correct?
A. Yes.
Q. And on the first page in the abstract, you can see the author's conclusions: "As compared with anterior colporrhaphy, use of a standardized trocar guided mesh kit for cystocele repair."
And that's the Prolift kit, right?
A. Correct.
Q. And that kit resulted in a higher short-term rate of successful treatment, but also in higher rates of surgical complications and postoperative adverse events.

Page 115

Is that correct?
A. That's what it states.
Q. And on page 1833 of the study, the authors discuss those adverse events.
Do you see the "Adverse Events" section?
A. Yes.
Q. And they note that the mesh repair group had a significantly longer mean duration of surgery.
Do you see that?
A. Yes, I do.
Q. The mesh repair group had a greater mean interoperative blood loss.
Do you see that?
A. Yes.
Q. And the mesh group had more frequent need for interoperative cystoscopy.
Do you see that?
A. Yes, I do.
Q. And those are all significant complications for the patient; is that fair?

Page 116

A. I don't think the cystoscopy one is. I pretty much do intraoperative cystoscopy on every patient.
Q. You do one cystoscopy rather than multiple, right?
A. Not necessarily, in my patients.
Q. If there was more frequent cystoscopy, at least these authors indicate that that's a increased adverse event associated with mesh-based repair; is that correct?
A. They're adding it, but in my uterosacral suspensions, my native tissue repairs, we actually do two cystoscopies in those procedures.
Q. And these authors note that: "Compared to native tissue repair, these authors note that compared to traditional colporrhaphy that the mesh group had more need for intraoperative cystoscopy at p-equals .006."
Do you see that?
A. I see that.
Q. And that's highly significant,

Page 117

right?
A. I see that's significant. I don't know if these doctors, if they did any such anterior colporrhaphy if they would cystoscope these patients. I would because there's data out there to support, to show that when you do an anterior repair, you can get cubital kinking from a native tissue repair.
Q. And the authors continue: "More bladder perforations occurred in the mesh repair group than the colporrhaphy group."
Do you see that?
A. Yes, I do.
Q. And the next sentence, or a little bit farther down the authors note: "The inguinal pain and bladder emptying difficulties during hospital stay were more common after mesh repair."
Do you see that also?
A. Yes, I do.
Q. And these authors were specifically looking at the Prolift kit; is that correct?

Page 118

A. They're doing more surgery here. I'm not surprised to see some more adverse.
Q. This study is specifically looking at the Gynecare Prolift kit?
A. I understand, but when you're putting in the mesh, you're still doing more surgery than you would be doing at a traditional anterior colporrhaphy.
Q. So these authors looked at implanting the Gynecare Prolift kit and found increases in all of these adverse events; is that correct?
A. That's correct. I'm not surprised to see that.
And if you look at the difference in greater mean intraoperative blood loss, 84 to 35, we're talking about not even two ounces of blood.
Q. So, these authors conclude that there's a greater risk of adverse events with the Prolift kit.
In your report, you discuss the Altman study on page 29 and on page 32.

Page 119

A. Okay.
Q. You don't appear to address these authors' conclusions.
As you sit here today, do you have a criticism of the authors' conclusions in the Altman study?
A. I don't have a criticism for them putting it in.
Clinically significant, once again, the mean intraoperative blood loss when we're going from a little over an ounce to a little less than three ounces is not clinically significant.
The more frequent need for intraoperative cystoscopy, once again not clinically significant.
And the duration of the surgery, I would expect it to last longer and that's what we would discuss with the patient because we are doing more surgery when we are putting in a transvaginal mesh than doing a simple anterior colporrhaphy.
Q. On page 1831 in Altman, the authors note that at the one year -- on

Page 120

the bottom right, you see: "The one year assessment symptoms of stress urinary incontinence were significantly more bothersome in the mesh repair group than the colporrhaphy group."
A. I'm aware of that.
Can you just show me the number we're talking about?
Q. It's on the -- it's p equals 0.02. So statistically --
A. You're talking about the UDIS subscale?
Q. I'm on the text on the far right column.
The authors in Altman note that there's increased stress urinary incontinence that's bothersome in the mesh group compared to the anterior colporrhaphy.
Right?
A. Yes.
Q. And the authors continue on the next page that: "New stress urinary incontinence occurred in 6.2 percent of

Page 121

the patients in the colporrhaphy group versus 12.3 percent in the mesh repair group, statistically significant."
Do you see that?
A. Yes, I do.
Q. And is that consistent with your clinical practice that stress urinary incontinence is more common with mesh as with colporrhaphy?
A. That's consistent with the data.
Q. And on that column on the right on that same page, the authors note that: "Pain during sexual intercourse was reported to occur usually or always by 2 percent of the women after colporrhaphy and by 7.3 percent after transvaginal mesh surgery."
Do you see that?
A. I see that. And the p-value's not significant.
Q. So, because the p-value's not significant, you would discount the Altman finding?
A. I wouldn't discount it, but it's

Page 122

not a significant finding.
Q. Is that finding of increased dyspareunia consistent with your clinical practice?
A. This is one study --
MR. ROSENBLATT: Object to form.
A. -- showing that.
And in my clinical practice, the dyspareunia rate is equivalent to the nature tissue repair -- native tissue rate.
THE WITNESS: Can we go off the record?
(Discussion held off the record.)
BY MR. BENTLEY:
Q. Doctor, are you familiar with studies by Milani?
A. Who?
Q. Milani, M-I-L-A-N-I.
A. Can you show me that study?
(Exhibit Winkler 12, Damoiseaux abstract, was marked for identification, as of this date.)

Page 123

BY MR. BENTLEY:
Q. Doctor, I'm handing you what's being marked as Exhibit 12.
This is a study by Damoiseaux, and this is in the International Urogynecological Association Application 2015.
Do you see that?
A. Yes.
Q. This is just an abstract entitled "Long-Term follow-up seven years of a randomized controlled trial trocar guided mesh compared with conventional vaginal repair in recurrent pelvic organ prolapse."
Do you see that?
A. Yes, I see that.
Q. And these authors were looking at an RCT of Prolift compared to conventional repair.
A. Let me take a second to read it.
(Perusing document.)
Okay. So I'm up to "Results."
Do you want me to -- you want to

Page 124

comment on any of that or just continue reading?
MR. ROSENBLATT: You can take your time and read the entire article, if you need to.
THE WITNESS: Okay.
(Perusing document.)
BY MR. BENTLEY:
Q. So, in your report on page 29 you discuss --
A. I'm not finished reading it, I apologize.
MR. BENTLEY: Well, if you want to go off the record, you can read literature.
THE WITNESS: Sure.
(Perusing document.)
Okay.
BY MR. BENTLEY:
Q. Doctor, in your report, you note that this study by Damoiseaux in 2015 found no differences in overall rates of dyspareunia between Prolift and the traditional repair; is that correct?

Page 125

A. Yes.
Q. Are you with me on page 29 of your report?
A. No, I'm sorry. I was looking at this. There was no difference in this study over here.
Q. But you don't cite their conclusion, their ultimate conclusion that alternative non-mesh treatments, including non-surgical, should seriously be considered.
A. I didn't -- I don't disagree -- agree or disagree with that. On this what I'm talking about in this paragraph over here is transvaginal mesh and dyspareunia specifically. So I cited it for that.
Q. So do you agree with their conclusion that alternative non-mesh treatments should seriously be considered?
A. Once again, I agree that appropriate counseling needs to be provided to patients who undergo transvaginal mesh procedures and that needs to take into consideration their

Page 126

goals and objectives for the surgical procedure.
Q. So you cite their finding about dyspareunia rates, but you don't address their conclusion in your report; is that correct?
A. My understanding is this litigation is not about the efficacy of a transvaginal mesh procedure, but it is regarding the complications of a transvaginal mesh procedure.
Is that not accurate?
Q. That wasn't my question.
You provide -- you cite a finding from this study in your report, but you don't address the authors' ultimate conclusion recommending alternative non-mesh surgical procedures; is that correct?
A. Once again, alternative non-mesh procedures should be discussed with each individual patient, and making a blanket statement that you should do other, and they don't say you should do other, that

Page 127

you should consider others, then that's what you need to discuss with your patients, and they don't say you shouldn't do the surgery. You should seriously consider it. And I agree with that, they can consider it. You need to consider all the risks and the benefits of a surgical procedure.
Q. So you should -- let me get it clear.
You agree with the authors' ultimate conclusion that you should seriously consider non-mesh treatments?
A. No, I agree with the author that you should seriously discuss non-mesh and mesh surgical treatments with your patients.
I agree -- I agree with the statement to start off, not to end. You should have this discussion with your patients before you do the surgery, not afterwards.
Q. One of the other conclusions at the seven-year follow-up, if you look a

Page 128

little farther up in that paragraph, is that the mesh exposure rate was extremely high.
Do you see that?
A. Yes, I do, and I was looking in the study to see what their exposure rate was.
Q. My copy is a little different, but in mine there's a chart 40 percent exposure.
Is that consistent with the copy you have?
A. Right. And you had a 7 percent exposure rate in the conventional group, which we have been talking about as -- you know, doesn't really happen. So how did they get their 7 percent there?
Q. So, my first question is you don't address a 40 percent exposure rate in your report, right?
A. Once again, we were not discussing that in this particular subsection.
These were patients who had

Page 129

anterior and posterior meshes and we prior discussed that I think if someone's going to have an anterior and posterior mesh that you may see up to a 24 percent exposure rate. So I don't know if 24 and 40 percent is going to be significant.
Q. In your report, Doctor, you cite the study, right?
A. Yes, I do.
Q. And you state: "7 year follow-up data was presented by Damoiseaux 2011 in abstract form and reported 10 percent de novo dyspareunia rate in the mesh group and 12 percent in the no mesh group."
Correct?
A. Correct, that's what's written in my report.
Q. In the next sentence you state: "There is no difference in overall rates of dyspareunia as well between the two groups."
Correct?
A. There is no statistically

Page 130

significant difference, and if you look at the paperwork from 2015, the p-value for dyspareunia and the p-value for de novo dyspareunia is nonsignificant.
Q. So in your report, you discuss the dyspareunia rate, but you don't discuss the exposure rate and you don't discuss the authors' ultimate conclusion, correct?
A. Once again, in this subsection, that was not called for here and that is not in my report.
Q. Because it didn't agree with your conclusion there?
MR. ROSENBLATT: Objection.
A. No.
MR. ROSENBLATT: Object to form.
A. My conclusion was, and they concluded it themselves as well, that there's no -- in their conclusions, there was no difference in pain or dyspareunia between the two groups. I am quoting that.
Q. That's one of their conclusions

Page 131

you cite in your report, right?
A. And I've never denied that there's an exposure rate that can happen with meshes and you need to take that into consideration.
Q. Nowhere else in your report do you discuss their 40 percent finding of exposure rate at 7-year follow-up.
And my question is why do you not discuss that?
A. It was not relevant to this subsection.
Q. You discuss exposure rates elsewhere in your report, right?
A. I discussed exposure rates elsewhere in my reports and I go with the overall gestalt. I did not include this in the exposure rate, that I am aware of.
Q. And the 40 percent exposure rate is well beyond any acceptable exposure rate you've testified to today, right?
A. This is higher than I would like to see, but this is one study only.
And once again, I'd like to

Page 132

know, and this is only in abstract form, how many of these were symptomatic, how many of these were not symptomatic, and what was the follow-up. Why didn't they include the -- if there was a significant number in patients going back to the operating room, they would have that, why wouldn't they put that in?
MR. ROSENBLATT: Greg, how much more do you have?
MR. BENTLEY: Do you want to take a break?
MR. ROSENBLATT: I think it would be good.
MR. BENTLEY: I'm fine with that. Let's do that.
(Recess taken from 6:27 p.m. to 6:33 p.m.)
BY MR. BENTLEY:
Q. Doctor, one of the bases for your opinions today that Prolift and Gynemesh PS is save and effective is your own personal clinical experience; is that fair?

Page 133

A. That's fair.
Q. And we discussed this a little bit earlier today regarding TVT, but you don't keep a case log for your prolapse patients, do you?
A. No, I do not.
Q. And you don't have any exact numbers for how many of your patients that you did a Prolift procedure with mesh suffered complications, right?
A. I don't, but I do have anecdotal follow-up on patients who have transvaginal mesh, I asked to return yearly to the office and I monitor them. And then once again, if anybody else was removing any of the transvaginal meshes that I placed, as a general rule, they probably would tell me. There are exposures that I went back on and had to revise. I'm not aware of any of my transvaginal mesh procedures where somebody went back in and had to remove the entire piece of mesh.
Q. So you don't know what

Page 134

percentage of your patients had a complication after Prolift, right?
A. So, my exposure rate is consistent with the literature. My reoperation rate as a whole is lower than, I think, the literature because these asymptomatic mesh exposures were not taking patients back to the operating room for as much these days.
Q. What's your exposure rate?
A. I would -- around 10 to 12 percent for each compartment that mesh is placed in.
Q. How are you reaching a 10 to 12 exposure rate, how do you have that estimate if you don't keep track of the number of --
A. So, I'm basing it just on patients that I've seen back, as well as the average numbers in the literature, but I'm basing it on the numbers of patients that I've seen.
We were participating in the 522 study for Elevate. Unfortunately, that

Page 135

was stopped because Astora went out of -- had closed down.
Q. Is that your own opinion, or was this told to you that the 522 order was stopped because Astora went out of business?
A. I mean, we participated in the study. They said we're going out of business, we're not funding the study anymore.
Q. If Astoria was not, in fact, out of business and their stock price was rising today, would that maybe change your opinion as to why the study was stopped?
A. I don't think the study was stopped for complications. I think the study was stopped for business decisions, monetary decisions.
I don't recall having to take back any of my patients who received mesh in that study back to the operating room.
Q. All right. So, we have your anecdotal recounts of your patients as one of the basis for your exposure rate,

Page 136

right?
A. It's the follow-up that I do with them yearly, yes.
Q. And we've discussed you don't actually have numbers for that, right?
A. Correct.
Q. And then another basis is your literature review, right?
A. Correct.
Q. And then the third basis that you just told me is your 522 study that you started regarding Elevate; is that correct?
A. Correct.
Q. And that study wasn't finished either, right?
A. No, it was not. Although no one's denying that mesh exposures happen with any times we put in meshes.
Q. I'm just trying to figure out what your personal experience with exposure rates would be because that's one of the bases for your opinions, right? But we don't have a number?

Page 137

A. We don't have an exact number. We need to go by the literature's number and my clinical experience.
Q. What's the robotic assisted sacrocolpopexy exposure rate that you're aware of or that's your opinion?
A. Well, we do the procedure with a super -- or, I do the procedure most commonly with a supracervical hysterectomy in order to avoid any incisions on the vagina. The rate reported in the literature for abdominal sacrocolpopexy with polypropylene mesh is anywhere from about a half percent to 3 percent, if I remember correctly. That may be based on a Schimpf -- is that on Schimpf from the meta-analysis?
THE WITNESS: Do we have that paper, Paul? Could we get that?
MR. ROSENBLATT: It's not printed out.
THE WITNESS: Okay.
BY MR. BENTLEY:
Q. Go ahead.

Page 138

A. And based on some older data that actually I think is quoted in my report. Let's see if we can find that Nygaard study with the polypropylene as opposed to the graft material.

MR. ROSENBLATT: It's Tab 39, if you wanted to see it.

THE WITNESS: Okay. Let's just see 39 here.

A. So, the most recent Cochrane review reports a mesh exposure of 3 percent. The erosion rate in the Nygaard paper included a bunch of patients who had woven polyester or Gore-Tex.

In 2008 Cundiff had a 5.1 erosion rate, but I'm going to the most common erosion rate in 2016 of only 3 percent. And we try to reduce that rate by doing, if we're going to do it as a primary repair, as a supracervical hysterectomy versus a total hysterectomy.

Q. So, it's your opinion that the sacrocolpopexy mesh exposure rate is approximately 3 percent?

Page 139

A. Correct.

Q. And that's based upon your reliance on the 2016 Cochrane report that we've reviewed; is that correct?

A. Primarily.

THE WITNESS: Can we get the Schimpf one printed out?

MR. ROSENBLATT: I could pull it up, but I can't print it out.

Do you mind if I pull it up for him?

MR. BENTLEY: That's fine.

MS. THOMPSON: We may have it.

THE WITNESS: You have the Schimpf paper, the 2016 meta-analysis.

BY MR. BENTLEY:

Q. If you're citing to that and that's your basis for it, that's all I'm trying to figure out.

A. Yeah, it's somewhere around the 3 percent. I think in the Schimpf paper it was lower, I just can't remember.

Q. And de novo dyspareunia with sacrocolpopexy, I think in your report you

Page 140

state that it's scarce; is that correct?

A. It's a low number with sacrocolpopexy.

Q. I think on page 31 at the top you state: "There's extremely limited data on the development of the available of dyspareunia after sacrocolpopexy attesting to the scarcity of it occurring."

Do you see that?

A. Right. And the recent Cochrane review was unable to report on the rate of de novo dyspareunia with an abdominal sacrocolpopexy.

Q. So based upon de novo dyspareunia, abdominal sacrocolpopexy is safer for the patient such that they're not at risk of developing dyspareunia de novo?

MR. ROSENBLATT: Object to the form.

A. Well, safer -- dyspareunia is not a safety issue. Dyspareunia is a quality of life issue.

Page 141

Q. So, with respect to sacrocolpopexy using mesh, there's a lower rate of de novo dyspareunia as compared to Prolift for women that are being treated for prolapse; is that correct?

A. There's a lower rate for sacrocolpopexy with trans -- as compared to transvaginal mesh, as well as native tissue repairs.

Q. Doctor, what do you mean in your report on page 33 when you state that: "A patient required wide mesh excision"? What's the significance of describing it as a wide excision?

A. Where in my report is that?

Q. I'm at the top.

Is there any significance to describing something as a wide excision?

A. I'm describing what they described. A wider mesh incision is probably removing more mesh than just cutting out a small mesh exposure. I'd have to look at that paper to get an exact -- an exact understanding of what

Page 142

they meant. So why don't we pull out the Landsheere paper 2001.
Q. I'm just asking you if there's any significance to describing it as a wide excision.
A. Wider than it was more -- more extensive of a dissection that was necessary than just a simple excision.
Q. Doctor, I think we've talked about it, but can you tell me again what you intend to testify as to the rate of dyspareunia for native tissue repair transvaginally?
A. So, that's going to depend on what's being performed at the transvaginal repair. If we're doing a posterior repair, there have been reports of up to 30 percent dyspareunia rates, if we're just doing an apical suspension or if we're just doing an anterior repair. So I would try to qualify what we're doing and in the repair and testify that native tissue repairs do have a dyspareunia rate and it's variable depending on the

Page 143

procedures performed.
Q. And what's your basis for stating that it's up to 30 percent?
A. I think the Paraiso study showed that it was almost up to a 30 percent de novo dyspareunia rate.
Let's see.
(Perusing document.)
Do you know where that Paraiso dyspareunia repair study is?
Q. You discussed the Paraiso at the bottom of page 27, it looks like.
A. But that's a different study.
There's a Paraiso posterior repair study comparing -- it's a Paraiso study of posterior repair. There was no trans -- I don't think there was transvaginal mesh. I think it was site specific versus porcine versus an anterior study.
Q. I'm trying to figure out what you intend to testify to as the dyspareunia rate for native tissue repair, and I believe you testified that it's up

Page 144

to 30 percent?
A. Yeah, I recall.
And I'd like to get that study out, if we can. Once again, I can't remember things by heart.
Q. Sure.
And you think it's Paraiso 2011 on page 39 of your report?
A. No, that's not it.
It's a Paraiso study on posterior repair comparing traditional colporrhaphy repair to -- to porcine, I think, and to cite specific.
Q. So, I think I understand.
Your testimony is that posterior repair has a higher rate of dyspareunia?
A. Yes.
Q. Okay.
A. How's that?
Q. And you think that's up to 30 percent?
A. So, I said it's been reported up to 30 percent. I don't see it that high, but it has been reported that high.

Page 145

Q. And as we've seen, there's a variation in rates reported in various studies, right, for various complications, right?
A. Agreed.
Q. And is 30 percent your average number, or is that on the high end of --
A. That would be on the high end.
Q. So what's actually the true rate of dyspareunia you intend to --
A. It depends on the patient that I'm operating on. It depends on the procedures that I'm performing. And it depends on the situation that's going on, if I'm doing abdominal sacrocolpopexy versus native tissue repair versus dyspareunia versus if the patient has atrophy already, do they have a painful intercourse already. It's so variable it's hard to pin down to an exact number of what the dyspareunia rate is going to be, and that's why it's so hard in the literature because there's so many variables that go into dyspareunia, and as

Page 146

time goes on, dyspareunia rates go up.
Q. I'm going to hand you what's being marked as Exhibit 13.
(Exhibit Winkler 13, Lowman article, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. It's a study that is by Joye Lowman entitled: "Does the Prolift system cause dyspareunia?"
Do you see that?
A. Yes.
Q. And these authors were actually trying to investigate this very question, right?
A. Correct.
Q. And the conclusion they have is that Prolift is associated with a 17 percent de novo dyspareunia.
Do you see that on top of the first page?
A. Yeah.
Hold on. Where is Lowman in my report?

Page 147

Q. 28.
But is that the conclusion from these authors?
A. Hold on. I just want to find it in my report, if that's okay.
(Pause.)
Okay. Go ahead.
Q. And these authors that evaluated dyspareunia with Prolift concluded there's a 17 percent de novo dyspareunia rate, correct?
A. Correct.
And in my report it says, and I was trying to find where it is: "As stated prior, native tissue posterior repair has significant risk of developing de novo dyspareunia. Therefore taking this in consideration, it seems that the 16.7 percent rate is consistent with the native tissue studies."
Q. I didn't ask you about that.
A. Okay.
Q. What's your basis for concluding that that's the rate for native tissue

Page 148

repair?
A. So, Paraiso in 1996 reported a 16 percent dyspareunia rate and -- after sacrospinous suspension.
I'm trying to find -- okay. Weber et al. 2000 reported of a de novo dyspareunia rate occurring in 26 percent of women after posterior colporrhaphy. Citation 54 in my report.
Q. So, is it your testimony that you think that's the true rate of de novo dyspareunia is figure for posterior repair?
MR. ROSENBLATT: Object to form; mischaracterization.
A. I'm saying in that study, she saw 26 percent rate of de novo dyspareunia occurring with posterior repair.
Q. Okay. So, let's be clear.
In response to the Lowman study that evaluates dyspareunia in Prolift, you just told me about a study from Weber from 2000 that found 26 percent dyspareunia in posterior repair; is that correct?

Page 149

A. I'm saying that posterior repair may have a higher incidence of de novo dyspareunia than anterior repair.
Q. And is the study that actually looked at Prolift de novo dyspareunia limited to posterior repair?
A. It's no.
But what I'm saying is many of these patients had a posterior mesh placed. So you need to compare those patients and the dyspareunia rate, if you're saying things are higher or lower, to the posterior repair rates that we have on native tissue.
Q. Let's try and compare apples to apples.
You're citing a study Weber 2000 that's specifically talking about posterior, right?
A. That's correct.
Q. Okay.
A. And if we look at John Gray 2014 where they performed the meta-analysis on patients who underwent an anterior or

Page 150

posterior native tissue repair and sexual function, which is probably more similar to the Lowman study, they reported an 18 percent worsening of dyspareunia postoperatively.
Q. You want to finish that sentence?
A. With a 4 percent de novo rate.
Q. So a 4 percent de novo rate in a study that you said is most likely similar to the Lowman study, a 4 percent de novo rate, that's what your report says, right?
A. They did show that, but with posterior repair with other studies, there has been a higher reported rate.
Q. So, the Lowman study that you cited and that looked at Prolift found a 17 de novo dyspareunia and you just read about a study that you said is most similar to it and found a 4 percent de novo rate.
My question to you is when you counsel your patients, do you tell them that the Prolift de novo dyspareunia rate

Page 151

is up to 400 percent higher with Prolift and Gynemesh PS or --
MR. ROSENBLATT: Object to form; lack of foundation; mischaracterization.
A. I base that on one study. This is one study. I base this on the Cochrane review which says that they're equal.
Q. You cited both of those studies in your report, right?
A. I did.
Q. In your report you state that there was a 4 percent de novo rate and you just characterized that study from John Gray as being most similar --
A. I said more similar.
Q. To Lowman, right? Because the other study you cited to, Weber, was specifically looking at posterior repair which necessarily has a higher dyspareunia rate, right?
A. So, I don't remember in John Gray of how many of these patients had posterior repairs, so I would need to look at that number. So we can look at that

Page 152

and then we can compare it to Lowman to see how many of them are posterior repairs, I guess.
Q. Do you have any other basis for stating that the de novo dyspareunia rate with Prolift is similar in native tissue repair besides the Weber, which is only posterior, besides John Gray, which only found a 4 percent de novo rate? Do you have any other studies for your basis?
A. The Cochrane review shows that they're similar with transvaginal mesh.
Q. As we already looked at the Cochrane review recommends against using the Prolift and Gynemesh PS repair as a primary surgical intervention for prolapse repair, right?
A. And I've agreed to you that transvaginal mesh is not the procedure for every single patient, correct.
Q. For the majority of patients, right?
MR. ROSENBLATT: Object to form.
A. That depends on the patient

Page 153

population, I guess, that you're seeing.
Q. The Cochrane review concludes that Prolift and Gynemesh PS in transvaginal-based mesh repairs shouldn't be used in most patients, if any; isn't that correct?
A. In 2016, they conclude that it should not be a primary repair, and I will agree with you it is not the most common primary repair that I perform in my patient population.
And in the Lowman study, I just would like to comment also that although the de novo dyspareunia rate was at 17 percent, there was still 83 percent of respondents with de novo dyspareunia would have the procedure done again. So although they were having some de novo dyspareunia, they would still do the surgery again.
MR. BENTLEY: I'm going to move to strike. That was not responsive.
I'm sure your counsel will clarify that.

Page 154

MR. ROSENBLATT: He was clarifying de novo dyspareunia.
MR. BENTLEY: He was not clarifying de novo dyspareunia.
BY MR. BENTLEY:
Q. Doctor, approximately how many Prolift kits do you think you implanted when it was still available?
A. Guesstimate about 50.
Q. And how many -- let's talk about how you would have got to the estimate.
How many transvaginal -- let's back up.
We did percentages.
On average, how many women are you treating per year for prolapse?
Let's go back even farther.
On average how many women do you see per year that are suffering from prolapse?
A. New patients or total?
Q. Total how many women do you see --
A. That's a hard number to answer.

Page 155

I would say five, six hundred.
Q. And of the five or six hundred women you see per year that are suffering from prolapse, how many of those women do you undergo a surgical intervention to treat the prolapse?
A. So, about 30 percent of the patients, somewhere along the line -- about 30 to 40 -- five, six hundred, 30 to 40 percent of patients somewhere along the line probably end up choosing surgery these days. Gross numbers.
Q. So, is it fair to estimate that you're performing approximately 200 surgeries, give or take, per year to treat prolapse?
A. Something like that, yeah.
Q. And we've already looked at approximately 50 percent of those per year would be --
A. So you're asking me what my numbers are today.
Back in 2005, '6, '7, '8, I was doing more transvaginal procedures than

Page 156

I'm doing today.
Q. When you first started using Prolift, were you still doing native tissue repairs at that time?
A. Yes.
Q. And did those native tissue repairs, whether it's obliterative or transvaginal-based implantation, did that group comprise approximately 50 percent of your repairs each year compared with your clinical practice today?
A. Sorry.
Q. Were 50 percent of your repairs in 2005, 2006 native tissue repairs?
A. No, I was probably doing more transvaginal mesh procedures and the -- it was lower on a native tissue procedure. So in my patient population, if we were doing a vaginal procedure, those were the most likely the patients that we were discussing transvaginal mesh and those patients would have chosen a transvaginal mesh. So the native tissue would be higher and the transvaginal mesh -- the

Page 157

native tissue would be lower and the transvaginal mesh number would be higher back then.
Q. So did you see approximately 200 patients per year, or did you surgically treat approximately 200 women per year that suffered from prolapse throughout your career, do you think?
A. Something like that, yeah.
Q. And you started using Prolift around 2006 or 2007, correct?
A. Something like that, yeah.
Q. And you began using the Boston Scientific kit once it was available because it had better apical support, right?
A. That's correct.
Q. And during that time frame when you used Prolift before the Boston Scientific kit was available, it's your testimony that you used a larger percentage of transvaginal mesh-based kits during that time period?
A. Than I do today, yes.

Page 158

Q. Did you also use a larger percentage of abdominal sacrocolpopexy procedures at that time?
A. I think that has increased over the years.
(Pause.)
(Exhibit Winkler 14, Halaska article, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. Doctor, I'm handing you what's been marked as Exhibit 14, and it's a study by Michael Halaska.
Do you see that?
A. Yes.
Q. I'll represent to you that this study is cited in your Gynemesh Prolift report on page 33.
A. Yes, okay.
Q. And on page 33 you cite this study for the proposition that: "Prolapse repairs have demonstrated no statistically significant difference in vaginal length or contraction, de novo dyspareunia,

Page 159

sexual function or pelvic pain."
Do you see that?
A. Yes, I do.
Q. And we've already looked at some studies that showed increased de novo dyspareunia with mesh which you disagreed with though, right?
A. Overall I disagree with, yes.
Q. And this study actually is titled "A multicenter randomized perspective controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of post-hysterectomy vaginal vault prolapse."
Do you see that?
A. The title?
Q. Yes.
A. Yeah, I see the title.
Q. And the conclusion is -- actually, in the results the authors note that the mesh exposure rate was 20.8 percent.
A. Yeah, and I like what the conclusion says: "Mesh exposure

Page 160

occurrence was balanced against a lower prolapse occurrence rate in the patients undergoing mesh surgery compared with those undergoing sacrospinous fixation."
Q. And what's your opinion as to what the acceptable exposure rate is?
A. We discussed before that on average if we're going to -- what we're going to see, we're going to see about a 10 to 12 percent exposure rate. This was a 20.8 percent exposure rate.
But let's check if this -- if they were anterior or posterior meshes placed.
Q. So, regardless, this study is evidence of an exposure rate higher than what you feel is the true exposure rate?
A. You're not letting me look through the study.
Q. My question, Doctor.
A. No, if there was mesh placed anterior and posteriorly, I previously testified that we may see up to a 24 percent acceptable rate.

Page 161

Q. So it's your testimony that the acceptable rate for anterior and posterior placement of mesh is 24 percent?
A. We're going to see it's at 10 to 12 percent in each compartment that we put mesh in and we, if we're going to put mesh in transvaginally in two compartments, then I would expect to see a higher rate.
Q. You would expect to see a 24 percent, is that your opinion?
A. If I add up 12 plus 12, you can get up to 24.
Q. I appreciate that. I'm trying to figure out what your opinion is and what you intend to testify to the jury.
Is it your opinion that if there's an anterior and posterior mesh repair, you intend to testify that the exposure rate is 24 percent?
A. I can say that you can see in up to a 24 percent exposure rate.
Q. I'm not looking for the highest possible range, Doctor. I'm just trying to figure out what your opinion is as to

Page 162

the true exposure rate of Prolift.
It's important for the safety profile, right?
MR. ROSENBLATT: Object to the form and the use of the "true rate."
Q. What's the actual rate of mesh exposure when implanting for anterior and posterior repair in prolapse, based upon your literature review?
A. So this was a study both anterior and posterior dissections of insertions where total mesh were performed.
So, you're going to see a higher exposure rate when you have a total mesh placed in anterior and posteriorly than if you're only placing it in one compartment.
Q. I appreciate that.
Based upon your literature review and your clinical experience, what do you anticipate the exposure rate to be for women that have had an anterior and posterior repair with mesh?
A. I think you can see somewhere

Page 163

around the 24 -- up to the 24 percent range, 20 to 24.
Q. Okay. And this study, Halaska found a 20 percent exposure rate, which is consistent with your testimony as to the exposure rate for anterior and posterior repair using mesh, right?
A. If you're going to place an anterior and posterior mesh in, yes.
Q. And this study there is a 12 percent revision?
MR. ROSENBLATT: Object to form. That misstates what the study finds.
A. Where do you see that?
Q. If you turn to 601.e5 you'll see at the bottom --
A. 601?
Q. 301. I'm sorry.
If you'll turn to 301.e5 on the very bottom right they note: "The vaginal mesh exposure after one year in the mesh group was 20.8 percent, one quarter of which were symptomatic."
Do you see that?

Page 164

A. Yes, I do.
Q. And then they note: Of the 20.8 exposures, 63 percent were treated by surgical resection."
Do you see that?
A. That's 10 of the 28. That's not the entire cohort.
Q. 62 percent of the exposures were treated with surgical resection, right? Of these exposures, 10 or 62.5 percent were treated by surgical resection, right?
A. Just let's go with the numbers.
20.8 percent as compared with the number of patients is --
Q. 28? We can see the percentages, Doctor.
A. 20 percent of -- I got to do 20 percent of 79. So it's about 14 patients. Okay. Now I got it.
So they're going to say 10 of the 14 patients were treated with surgical resection. However, it states that only one quarter were symptomatic.
So why were they doing surgery

Page 165

in asymptomatic patients?
Q. What question are you answering, Doctor?
A. I'm just commenting on the study that we're talking about.
Q. I didn't ask for you to comment on the study. I appreciate that. I'm sure we'll have plenty of comment coming up.
20.8 percent of the women in the study had exposure, correct?
A. Correct.
Q. And of those 20.8 percent of the women that had exposure, 62.5 percent of them underwent surgical resection, right?
A. Okay.
Q. And so 63 percent of 20 percent is approximately 12 percent, right?
A. So, 10 of the 80 patients, 10 of the 79 patients, I think that's where you're getting your number from, right?
Q. I'm not counting patients.
What's .62 times .2?
A. I understand how you're getting

Page 166

to that number.
So 12 percent.
Q. So just do you agree with me that in this study specifically, they found approximately a 12 percent revision rate?
A. I do and I will comment that it seems that they were operating on patients who were asymptomatic with their exposure.
Q. And those patients that chose to undergo a surgical revision procedure decided to do that, right?
A. We don't know if they chose to do that or it was recommended by their physician at the time.
Q. Patients have to undergo a consent process for a surgical revision, right?
A. Yes.
Q. It's their decision whether or not to undergo a revision surgery, right?
A. Agreed.
Q. So these patients, for whatever reason, decided to undergo a revision

Page 167

procedure, right?
A. So, our understanding at this point in time, and I've stated this myself, that we were doing some surgical procedures on asymptomatic patients when we thought the mesh exposure needed to be removed, and we subsequently learned that you don't need to operate on every single mesh exposure. I can't comment -- all I can comment here is that one-quarter of them were symptomatic. So only five percent of the patients were symptomatic. So if 5 percent of 80 is symptomatic, it's a lower number than 10.
Q. You're critical of women choosing to undergo a surgical revision procedure because they have mesh sticking out of their body?
A. I'm not critical of that.
Q. They chose to do that, right?
A. I'm saying it's not absolutely medically necessary, but they can choose --
Q. But they can choose that, right?

Page 168

A. But I don't know what the counseling was with these patients. That's what I'm testifying to.
MR. ROSENBLATT: Let's slow down for the court reporter.
BY MR. BENTLEY:
Q. You know that 20.8 percent of the women had mesh sticking out of the body, right?
A. It was in the vagina. They may not even have known it.
Q. And 12 percent of the women decided to have the mesh that was sticking out surgically removed, right? Twelve percent of all of the women in this study chose to have mesh that was sticking out surgically removed?
A. Yes.
Q. So it's a 12 percent surgical revision in this study, which whether or not it was symptomatic, still 12 percent of the women underwent a revision surgery, right?
A. And once again, there is no

Page 169

question and I'm not going to doubt that patients do need to go back to the operating room for exposures.
Q. What's your opinion as to the rate of surgical revision for women that undergo Prolift repair, for anterior and posterior?
A. What's the percentage of patients undergoing revisions?
Q. Yes.
A. I don't have a total number for that.
Q. Do you have an estimate or an opinion as to what the revision rate is for patients that undergo an anterior only Prolift repair?
A. I would think that the revision rate is going to be somewhere around -- it's a hard question to answer because it depends on if patients were symptomatic and if the patients were sexually active and if it was bothersome to them. So I can't give an exact number, but I -- or an exact percentage because it depends on the

Page 170

patient population that you're choosing, but it's going to be lower than the exposure rate.
Q. So something lower than 20 percent?
A. Well, we discussed already that I think that if it's in one compartment, that was your question, that it's about a 10 to 12 percent. So I think it's going to be a somewhat lower than a 10 to 12 percent number that was quoted in this study. And once again, they had mesh placed anterior and posterior.
Q. Then with respect to the posterior repair, do you have an opinion or estimate as to what percentage of women undergo a revision procedure?
A. For posterior only, I would say somewhere around, once again the exposure rate is somewhere in that vicinity and that range that -- and then it would be lower as well for posterior than the 10 to 12 percent.
Q. What vicinity or range?

Page 171

A. The mesh exposure rate of about 10 to 12 percent per compartment.
(Exhibit Winkler 15, The American College of Obstetrics and Gynecologists Committee Opinion, Dated December 2011, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15.
This is the committee opinion from AUGS and ACOG dated December 2011; is that correct?
A. Yes.
Q. You're familiar with this opinion, right?
A. I just got to remember -- let me look through it a second.
(Perusing document.)
Yes, I'm familiar with this.
Q. And did you review this opinion in preparation of your Prolift and Gynemesh PS report?
A. Yes.

Page 172

Q. And you're a member of these societies, right?
A. Yes.
Q. They're reputable societies, right?
A. Yes.
Q. And this committee opinion is titled "Vaginal Placement of Pelvic Mesh For Pelvic Organ Prolapse"; is that correct?
A. That is correct.
Q. And on page 4, ACOG and AUGS are answering the question: "Who are the best patients for transvaginally placed mesh?"
Do you see that?
A. Yes.
Q. And the authors note that: "Few data exist as to who are the best patients for transvaginally placed mesh."
Is that correct?
A. I agree with that statement.
Q. And this is in 2011, right?
A. That is correct.
Q. Okay. Five years before the

Page 173

Cochrane Maher review that we looked at today, right?
A. That's correct.
Q. And the authors continue: "Pelvic organ prolapse vaginal mesh repairs should be reserved for high risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures."
Is that correct?
A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve outcomes for anterior repairs -- in the anterior compartment, excuse me, and they're commenting on that back in 2011 too.
Q. What question were you answering?
A. You were telling me --

Page 174

Q. Did I read that correctly, Doctor?
A. You read that correctly.
Q. And is that conclusion consistent with what the Cochrane review five years finds after reviewing 37 RCTs?
A. Well, that's why I was mentioning what the Cochrane review said, that there has been shown to be subjective and objective outcomes in the anterior compartment using transvaginal mesh in the Cochrane review.
Q. ACOG and AUGS in 2011 concluded that mesh like Prolift and Gynemesh PS placed transvaginally should be reserved for high risk individuals; is that correct?
A. I don't know if they concluded that. It doesn't say. I think that is one of their -- it's a --
Q. Well, let's look at it again. They state: "Pelvic organ prolapse vaginal mesh repair should be reserved for high risk individuals."

Page 175

Correct?
A. So we're going to look under "Recommendations"?
What page are you on?
Q. We're still on page 4.
A. Yes, so they were saying who are the best patients for transvaginally placed mesh and if you look on the following page that --
Q. Hold on.
A. Okay.
Q. Stick with the question.
They state: "Pelvic organ prolapse vaginal mesh repairs should be reserved for high risk individuals in whom the benefit of mesh placement may justify the risk."
Correct?
A. That's in every single patient. You're going to run a risk-benefit profile with them, and you want to try to do a procedure where the benefits outweigh the risks, yes.
Q. Every single individual is not

Page 176

high risk, are they? Is that your testimony?
A. Every single individual is not high risk.
Q. Right.
A. I am trying to quantify what high risk is.
Q. Well, the authors here state that the mesh should be reserved for high risk individuals, right?
A. Yes.
Q. Okay. And they're making a delineation that this mesh isn't for everybody; isn't that fair?
A. I've never -- I've always said that this mesh is not for everybody.
Q. Right.
A. Not disagreeing with you there.
Q. So you agree with their opinion that pelvic organ prolapse vaginal mesh repair should be reserved for high risk individuals?
MR. ROSENBLATT: Object to form. And just the lack of the completeness.

Page 177

A. I agree that the pelvic floor mesh is not for everybody. Their recommendation is to reserve it for high risk individuals and who the benefit of mesh placement may justify the risks.
They don't define what a high risk individuals is, but later on they'll give such as individuals with recurrent prolapse or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures.
Just because you have recurrent prolapse doesn't mean you're a high risk patient in a surgical procedure.
Q. And I appreciate that.
And you agree with that conclusion, is what you're saying?
A. I agree you need to take that into consideration when you are discussing your transvaginal mesh procedures with your patients and I think that is why we're doing the 522 studies today.
Q. Let me re-ask it.
Doctor, do you agree or disagree

Page 178

with their statement?
A. I agree, with a modifier. And my modifier is what is considered high risk? And that is where you need to have that discussion with the patient. are you considering high risk medical comorbidities? Are you considering high risk age? Are you considering high risk recurrence? How are you defining the high risk? And they gave some guidance, but not absolute guidance.
Q. You would think that -- let's say this.
You probably have the same definition of high risk as ACOG and AUGS in this circumstance, don't you, Doctor?
A. You're asking me to make an assumption, and I've stated that yes, transvaginal mesh should not be placed in every single patient.
Q. It should be reserved for high risk individuals, and we can talk about the definition of that, but you agree with that conclusion?

Page 179

A. It should be reserved for patients who you have a discussion of the risk-benefit profile to see if -- and they say that too, where the benefit of mesh placement may justify the risk.
Q. That's the standard risk-benefit discussion for every product for every patient, the risks should not be outweighed -- the standard risk-benefit discussion is that the benefits should always outweigh the risks.
There's nothing controversial about that, right?
A. And they further go on to say the repair of POP should take into account the patient's medical and surgical history, severity of prolapse, and patient preference after education regarding the benefits and risks of the surgical and non-surgical alternatives.
Which I agree with.
Q. And based upon that, it should be reserved for the high risk individuals is their conclusion that you just looked

Page 180

at, and I just want an answer, do you agree with the statement or disagree and why?
A. Once again, I agree that it should be reserved in high risk, but you got to define what high risk is.
Q. Thank you. Totally agree.
Doctor, you're familiar with this opinion, right?
A. Yes.
Q. Why don't you discuss this opinion in your report?
A. This is intuitively known that you should be discussing risks and benefits of particular procedures with patients. You said it yourself.
Q. Why don't you discuss the statement that this mesh should be reserved for high risk individuals that you've just testified you agree to, why don't you discuss that in your report?
A. I think I mention some of that stuff in my report.
So let's go to that.

Page 181

(Pause.)
Q. I don't think it's in your report, and my question is why isn't it in your report? But I could be --
A. It's there.
(Pause.)
A. So, I'm trying to find it for you because --
Q. Well, it should be there, is what you're saying, right?
A. Hold on. I'm going to find it for you.
The rationale for me, page 16.
Q. Okay.
A. (Reading) "The rationale for me was to use permanent mesh for patients who had failed a prior prolapse procedure or for post-hysterectomy patients with prolapse who were poor candidates for or did not desire an abdominal procedure."
Q. First of all, that's not quoting or citing the ACOG or AUGS committee opinion, right?
A. It's taking all this in

Page 182

consideration.
Q. I appreciate that.
There's a lot of footnotes, we've looked at a lot of them in here. There's 106 footnotes, right? Right?
A. Yes, there's 106 footnotes.
Q. And nowhere in those 106 footnotes do you cite to this committee opinion, right?
A. Although you can extrapolate that that opinion is consistent with my use of the mesh and I'm stating that.
Q. And that opinion is consistent, or you've testified that that opinion is consistent with your opinion, right?
MR. BENTLEY: Let me rephrase that.
Q. You've testified that you agree with that opinion, right?
A. I agree that you need to define what a high risk patient is and then you can have that discussion with them.
Q. And once you define high risk patients, the mesh should be reserved for

Page 183

them and not the other patients, right?
A. So, I can't comment on anybody else who -- what they're counseling their patient about when they use a transvaginal mesh procedure. I can comment what they should be counseling their patients about, but I can't actually sit in the room with every single doctor when they're talking about transvaginal mesh with their patients.
Q. When you counsel your patients, do you tell them that you think transvaginal mesh should be reserved for only high risk individuals?
A. We have a risk-benefit discussion of why they may benefit from transvaginal mesh as opposed to a native tissue repair, and if they're a high risk individual with previous abdominal surgeries, I would try to discuss with them where the risks and the benefits are and I would not make a blanket statement that you should only put mesh in this kind of patient, the same way I wouldn't make a

Page 184

blanket statement that you should put mesh in every patient.
Q. Would you like to add a citation to that conclusion to your report today?
MR. ROSENBLATT: Object to form.
It is included on his reliance list.
BY MR. BENTLEY:
Q. You can answer.
A. I think I explained it how I interpret that information, and the jury can take a look at that ACOG report and make their decisions.
Q. So would you like to update your report to add that conclusion to your report as one of your opinions in this case?
A. I don't think I need to update and use that word specifically because I think I've already stated that in my report.
Q. But you direct quotations from other studies in your report, right?
A. I do do direct quotations.

Page 185

And once again, you can take this information and bring it to the jury.
(Exhibit Winkler 16, Dandolu article, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. Doctor, I'm handing you what's been marked as Exhibit 16. This is a study from Dandolu 2016.
A. Yes, I see it.
Q. And you're familiar with this study?
A. Yes.
Q. And you cite this study on page 33 of your report?
A. Yes.
Q. Okay. And this study is titled "Mesh Complications and Failure Rates After Transvaginal Mesh Repair Compared With Abdominal Or Laparoscopic Sacrocolpopexy and to Native Tissue Repair in Treating Apical Prolapse."
Is that correct?
A. That's what the title reads,

Page 186

yes.
Q. And these authors conclude, as indicated in the right column in the abstract, that: "Reoperation for apical prolapse is more common with transvaginal mesh repair than with sacrocolpopexies and native tissue repair."
Do you see that?
A. That's what it states, yes.
Q. And they continue: "Incontinence procedures are more likely to fail when performed along with prolapse repair than when performed alone." And the next sentence is: "When mesh is used for repair, mesh revision is highest with transvaginal mesh repair and lowest with abdominal sacrocolpopexy."
Is that correct?
A. That's correct.
Q. And that's consistent with what we've talked about today and with your personal experience, correct?
A. Yes.
Q. In your report on page 33, you

Page 187

discuss the Dandolu study, but you don't discuss their conclusions regarding higher reoperation rate.
A. Once again, I was focusing on the title of that subsection of "Transvaginal Mesh and Pain."
Q. Right. And you provided a finding from the study regarding pain, but you didn't address the authors' conclusion that reoperation was higher with mesh placed transvaginally than with the abdominal sacrocolpopexies, right?
A. Once again, because this was not discussing efficacy. This was discussing complications.
Q. Doctor, if you can please turn to page 219 to the "Discussion" section.
A. Okay.
Q. And the authors in Dandolu are discussing the results, and three sentences in they note that: "Contrary to the popular notion that mesh used decreases surgical failure, we found higher reoperation rates with vaginal mesh

Page 188

used compared with native tissue repair."
Do you see that?
A. I see that.
Q. I think it's your opinion that transvaginal mesh has similar efficacy rates as compared to native tissue repair; is that correct?
A. So, transvaginal mesh in the anterior compartment has been shown to have greater subjective and objective outcomes. It has not been shown, and I'm going to agree with you and agree with the study, that for apical, which is where they're talking about, reoperation apical prolapse as per the Cochrane review, has not been shown for that. I agree with that statement.
Q. So an apical prolapse repair, native tissue repair is more efficacious than transvaginal mesh; is that correct?
MR. ROSENBLATT: Object to form.
A. Say that again.
Q. In apical repair, native tissue repair has a lower reoperation rate as

Page 189

compared to transvaginal mesh?
A. I didn't say that. I said that they -- that there's no proven benefit. That doesn't mean that the failure rate is worse, right, in the Cochrane review.
So, in the Cochrane review, if they say there's no significant benefit of -- of apical prolapse showing that it's better than native tissue repair, it doesn't mean it's worse.
Q. Well, this study we saw they found higher reoperation rates with vaginal mesh compared to native tissue repair, right?
A. In this one study, yes.
Q. And this study is looking -- it's your testimony this study is looking at apical repair?
A. That's what they said, reoperation for apical prolapse in the conclusion is more common with TVMR than with sacrocolpopexies. That's their conclusion.
Q. Right.

Page 190

And they continue to discuss that: "Postoperative mesh complications were higher than mesh use particularly when combined with incontinence sling surgery."

Do you see that?

A. They say they found higher reoperations rates with vaginal mesh used compared with native tissue repair.

So do I -- I am going to assume, and we can go look at the numbers, that the reoperation rates were for recurrence as well as mesh exposures, but --

Q. And in addition to reoperation rates, I moved down a little bit in that paragraph, they're also talking about complications.

Do you see where they say: "Postoperative mesh complications were higher with vaginal mesh use"?

A. Yes, I do.

Q. So, in addition to a higher reoperation rate with the mesh, they also found a higher complication rate compared

Page 191

to native tissue repair; is that correct?

A. In this study, they did, yes.

However, since we're talking about studies and what's there, it says: "Postoperative pain and dyspareunia rates were high in all types of prolapse repairs." Further down it goes to say: "Pelvic pain and dyspareunia are well-known complications of the POP procedures."

MR. BENTLEY: Again I move to strike the answer beyond what was responsive to my question.

MR. ROSENBLATT: He's just explaining his answer.

MR. BENTLEY: He's just reading the rest of the article which is --

THE WITNESS: You're picking out parts that you want to say.

BY MR. BENTLEY:

Q. So, there's several findings in this study we've discussed.

A. Yes.

Q. And you don't discuss any of

Page 192

those findings in your report, correct?

A. I do. In my report I do discuss that pelvic pain and dyspareunia rates are similar with vaginal mesh procedures.

Q. That's one of the findings from the study, and that's the only finding you discuss in your report, is that correct, from the study on page 33?

A. Overall in the study, I have always maintained that transvaginal mesh has been shown to have better subjective and objective outcomes only in the anterior compartment. We do not have data proving that it has better objective or subjective outcomes in the apical compartment or the posterior compartment.

Q. I'm going to re-ask my question.

In your report on page 33 where you're discussing the Dandolu 2016 study you discuss the pain findings, correct?

A. I do discuss the pain findings.

Q. And you don't address the finding that mesh was associated with a high reoperation rate, do you?

Page 193

A. Once again, not in this subtopic of what we were discussing. This was not a report on the -- or a component of the report of the efficacy of apical repairs here.

Q. Nowhere else in your report do you discuss that finding, do you?

A. Which finding?

Q. That vaginal mesh is associated with a higher reoperation rate as compared to native tissue repair.

THE WITNESS: Can you do a search of my report?

Q. I did. It's page 33. That's it.

A. No, I mentioned before that operation rates with exposures, if you take them into consideration, it's higher.

Q. I'm not talking about other operation rates.

A. You're asking me for a total operation.

Q. In this study that you cited in your report, you provide a discussion of

Page 194

the pain rate, but you don't discuss the higher reoperation rate with transvaginal mesh, do you?
A. Not for this particular study. However, I have quoted that in other studies, and the higher reoperation rate is including exposure rates.
Q. Likewise in your report on page 33 where you discuss this study, you also don't mention that postoperative complications were higher with transvaginally-placed mesh, do you?
A. I'm not denying that there's going to be a higher complication rate when you put in a synthetic. We know that already. Overall, it's more surgery, you're putting in a foreign body. It is intuitively and commonly known that your complication rate is going to be slightly increased.
However, the dyspareunia and pain rates do not seem to be increased.
Q. Doctor, you don't discuss in this section in your report on page 33

Page 195

where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no?
MR. ROSENBLATT: Object to form.
Are you only asking about page 33 or --
MR. BENTLEY: Anywhere in the report. Nowhere else in the report does he discuss it.
MR. ROSENBLATT: Look on page 21.
MR. BENTLEY: That's Dandolu?
Counselor, are you testifying that on page 21 the doctor discusses Dandolu?
MR. ROSENBLATT: No.
MR. BENTLEY: Okay.
BY MR. BENTLEY:
Q. On page 33 --
MR. ROSENBLATT: You're talking about a conclusion.
MR. BENTLEY: I'm talking about

Page 196

cherry picking a finding from one study in 2016.
On page 33, there's only favorable finding for him and he ignores all the other ones, which is called cherry picking. I'm just trying to lock that down.
MR. ROSENBLATT: All right. Sorry for interrupting. I was trying to help.
MR. BENTLEY: I mean, if there's somewhere else in the report, I stand corrected.
Is Dandolu cited somewhere else? Discussed somewhere else?
MR. ROSENBLATT: Look, I'm not going to argue with you. You can keep asking your questions.
I didn't know if you were talking about the study or the conclusion because he does discuss that conclusion.
MR. BENTLEY: I think the question's clear.

Page 197

BY MR. BENTLEY:
Q. On page 33 --
A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33.
Q. Thank you.
A. How does that work?
Q. A lot easier, to answer your question.
A. With the caveat that that was not what I was looking for in that subtopic.
Q. Because you were looking for cherry-picked findings in that subtopic?
MR. ROSENBLATT: Object to form.
A. I was not looking for cherry-picked findings. I quote the Cochrane reviews, and I've admitted to you here today that there has been no proven benefit for apical and posterior repairs. And even according to the Cochrane review there's been a benefit on anterior subjectively as well as objectively. And that's consistent with this paper.

Page 198

MR. BENTLEY: I move to strike. There's no question pending.
BY MR. BENTLEY:
Q. Let's look at the conclusions on page 221, Doctor.
A. Okay.
Q. The authors begin with: "Pelvic pain and dyspareunia are common complaints after prolapse surgery."
And that's consistent with your report and your testimony, right?
A. Yes.
Q. They continue: "Mesh revision is highest with transvaginal mesh repair and least common with abdominal sacrocolpopexy without concomitant sling."
Correct?
A. Okay.
Q. And that's the findings we've been discussing, right?
A. That's true.
Q. And they continue: "Reoperation for apical prolapse is more common with transvaginal mesh repair than with

Page 199

sacrocolpopexies."
And that's what you've been testifying to also, right?
A. I testified in this study that they did have a higher recurrence rate with the transvaginal mesh, yes.
Q. And they continue: "Overall, failure rate as measured by any type of subsequent prolapse surgery and/or pessary use is also higher with transvaginal mesh repair compared with sacrocolpopexies."
Do you see that?
A. I do see that.
Q. And do you agree or disagree with that finding?
A. I agree, but they did not -- they did not specify on the anterior vaginal wall of where I know where transvaginal mesh has shown subjective and objective. They're doing an overall and they're including their apical. So I haven't really gone through with that.
Q. So you agree --
A. That the overall failure rate

Page 200

was higher in this study. I agree with that.
Q. And to wrap up on this study you don't discuss any of those conclusions on page 33 where you discuss one finding from this study or anywhere else in your report, right?
A. So, in my practice I wouldn't even compare sacrocolpopexy to transvaginal mesh. My patients who are getting the sacrocolpopexy likely would not be candidates for transvaginal mesh.
Q. On page 33 where you discuss one finding from the study, you don't address any of these authors' conclusions, do you?
A. On page 33 I do not address those findings.
Q. And nowhere else in your report do you discuss the study one way or another, right?
A. Other places of my report I do discuss the -- where the benefits of mesh are and where there are none.
Once again, I would not even

Page 201

entertain to compare sacrocolpopexy to total transvaginal mesh. They are different patient populations that you would do that on.
Q. This is a published article. Someone thought it was worth doing a study and they got published on that very issue, right?
A. I agree. I agree.
Q. And there's fairly strict criteria to get an article published; is that fair?
A. I didn't say it was a bad study.
I'm just saying that in my patient population, patients who are candidates for sacrocolpopexy are usually not great candidates for transvaginal mesh, as per the ACOG guidelines which you showed me.
Q. I just need to clean up a little. I think I asked you these questions in the previous deposition.
But, Doctor, in your experience, do you treat women who have suffered

Page 202

complications after prolapse repair with transvaginal mesh?
A. Yes.
Q. And in your experience treating those women, have you ever seen mesh that's bunched?
A. Yes, I have.
Q. Were you able to visualize or feel the mesh being bunched prior to doing a revision surgery, or how did you observe that?
A. So, I can't tell just by feel if mesh is bunched. When we go back in and remove some of the mesh, I can see that mesh is bunched up.
Q. And do you have an estimate of how many times you observed that?
A. I don't have an estimate for that from when I went back in and do these procedures.
Q. How many women do you think you've treated for complications from having Prolift or Gynemesh PS transvaginally implanted?

Page 203

A. If I had to guess, around 20.
Q. And how many times do you think you've observed bunched mesh out of 20 women that you've treated for complications from these devices?
A. I can only specifically recall of one episode. I don't remember ones from years ago.
Q. Doctor, have you ever seen, and this may be the same, have you ever seen mesh that's roped when you were treating women that have complications from these devices?
A. I haven't seen the entire mesh ending up rope -- in one roped.
Q. Have you seen part of the mesh roped?
A. I've seen part of the mesh bunched. I don't know if you want to call it bunched, roped.
Q. Would you also say it's curled, is that another word for the same condition?
A. I think you can use that term,

Page 204

if you'd like.
Q. When a mesh bunches, ropes or curls, does that increase or cause pain for the woman?
A. I don't think roping or curling will cause pain in specific, but I do think that increased tension on tissues may cause pain.
Q. If the mesh is bunched, roped, curled, does that change the pore geometry of the mesh?
A. It may. It may not. Don't know.
Q. If the pore geometry is changed such that the mesh's pores collapse, does that change the, potentially change the inflammatory response?
A. So, I have not significantly seen pores collapsing with these transvaginal meshes.
You know, I have a really nice picture to show that we submitted of a transvaginal mesh that was placed and then that failed. It was an apical failure.

Page 205

THE WITNESS: Do you have the picture?
A. There are not too many pictures that we're going to have on meshes that we don't take out for complications, but you --
Q. So, if a mesh collapses, the pores -- if the pores collapse after roping or curling, is it your testimony that that doesn't affect the inflammatory response?
A. No. If the pore size, for some reason, gets smaller, it may affect the inflammatory response.
Q. And ultimately that could increase scarring and potentially cause encapsulation?
MR. ROSENBLATT: Objection.
A. I don't know if encapsulation occurs, but potentially it can, but usually we don't see encapsulation with these types of tissues because that would mean there's no tissue incorporated in the mesh. So quote/unquote encapsulation is a

Page 206

little different than --
Q. You don't want to see encapsulation; that's kind of a bad thing, right?
MR. ROSENBLATT: Object to form.
A. Encapsulation means to me that the mesh has not integrated into tissues, into tissue really. So that's the way I define encapsulation.
So I don't -- I can't define encapsulation if your mesh -- if a mesh bunches up and why not, because there is still tissue ingrowth into the mesh. They're not two separate -- there's still tissue in mesh.
Q. When we were talking about the Gore-Tex meshes, you said encapsulated and that was a problem, right?
A. Right, because there can be no tissue ingrowth with a Gore-Tex mesh.
There's still tissue ingrowth if I've seen mesh, quote/unquote, bunched.
Q. It may be decreased if it's encapsulated, to some extent?

Page 207

A. If it would be encapsulated, it would be an easier removal and dissection.
So we don't see encapsulation of these polypropylene meshes. I know it's been used, but by the strict definition, you don't see that kind of encapsulation.
Q. Well, me personally, I don't see any of it, but you haven't seen it in your clinical practice, you haven't seen any encapsulation of mesh?
A. If it's encapsulated, I don't need to do any dissection around the mesh, and that does not happen when these meshes are folded on each other.
Q. Doctor, let's look at page 14 of your report.
A. Okay.
Q. And this is a screen shot.
Where is that from? Where did you get this screen shot from?
A. I can't remember where I got that from.
Q. Did you take this screen shot yourself?

Page 208

A. I can't remember where I got that screen shot from. I have pictures of meshes and whatnot, so I can't remember where that came from.
Q. What about the mesh characteristics table above, do you know where that's from?
A. I think it's from Ethicon data, but I can't remember where it was from.
Q. Do you have any independent basis other than this screen shot to verify any of those numbers?
A. Well, there's other papers that -- let me see. I think this is based on Ethicon data, if I remember correctly.
Q. Could it be from marketing advertisement?
A. It could be. I don't remember where it was from.
Q. But it's not from a study?
A. Not that I recall.
Q. And there's three columns here. It's providing mesh characteristics for three different mesh, correct?

Page 209

A. Correct.
Q. And the first one is Gynemesh PS or Prolene Soft, right?
A. Yes.
Q. And that's one of the meshes that you were using to treat prolapse, right?
A. Correct.
Q. And that's next one's Prolene mesh; is that correct?
A. Correct.
Q. And is it your understanding that that's the mesh that's in the TVT products for stress urinary incontinence?
A. You told me before that there are a bunch of different types of Prolene meshes, but as a overall, yes, I would say that it's more consistent with the Prolene mesh as opposed to the Gynemesh.
How's that?
Q. And let's look at the second row. It says "Unit Weight." It's milligrams per centimeter squared, I believe. And it looks like the

Page 210

Gynemesh PS is listed as 4.36 and the Prolene mesh is almost double at 7.6.
Is that correct?
A. Yeah, the fiber size is different in the Gynemesh PS at like 3-and-a-half mil and in the Prolene mesh it's 6 mil.
Q. So that's going to make it heavier, or it's going to make the Gynemesh PS lighter than the Prolene mesh that's in the incontinence product, right?
A. Yes.
Q. One row below, that's the porosity. You can see the percent of total area, which is, I guess, an estimate of the porosity.
But in your report you discuss the Amid classification of largest pore size, right?
A. Yes.
Q. But the porosity here based on percent total area is 65 percent for Prolene Soft versus 53 percent in Prolene for the TVT, right?

Page 211

A. Correct.
Q. So the Gynemesh PS has a higher porosity than the incontinence products?
A. Correct.
Q. The burst strength, do you have any understanding what the burst strength is?
A. Yes, it's the type of pressure to put on that will burst out the mesh.
Q. How is that -- do you know how that's different from the tear strength?
A. Tear strength is pulling on the mesh.
Q. And what's the burst strength?
A. Would sort of be pushing on the mesh.
Q. So the Gynemesh PS is half as strong as the Prolene mesh as measured by burst strength; is that correct?
A. That's correct.
Q. And they're both implanted in the pelvis, right?
A. For different reasons.
Q. They're both in the same pelvic

Page 212

area, right?
A. For different indications.
Q. And then the tensile strength is also -- the tensile strength also shows that the Prolene Soft or Gynemesh PS is -- has half the tensile strength as the Prolene which is used in TVT; is that correct?
A. That's correct.
Q. And have you ever seen any documents discussing whether Ethicon's meshes are over-engineered or too strong for the -- unnecessarily too strong for the area where they're implanted?
A. I'm familiar with documents that Ethicon was looking to see, as we discussed before with the VICRYL mesh, to see if there were ways to improve their TVT sling.
Q. In the ETH.MESH documents that were provided to you, do you see anything where the company was evaluating whether their meshes were over-engineered?
A. What do you mean by

Page 213

"over-engineered" am I looking for?
Q. Well, you know that these meshes were developed for hernia repair, right?
A. Correct.
Q. And you understand that the abdominal region has different forces than the pelvic region, right?
A. Correct.
Q. And if the abdominal -- a repair in the abdominal region may necessitate a stronger mesh as compared to the pelvis, right?
A. It depends what the indication is for why you're using the mesh, and the TVT data has overwhelmingly shown safety and efficacy with this Prolene mesh.
Q. So you haven't been shown any documents discussing whether or not the mesh was over-engineered for use in the pelvis?
A. I don't remember the word "over-engineered."
I do remember documents that they were looking to see what a

Page 214

lighter-weight mesh would, would different meshes work, you know, what's out there always to improve on your product.
Q. I'm just jumping around a little bit to try and finish up.
A. No problem.
MR. ROSENBLATT: Can we go off the record for just one second?
MR. BENTLEY: Sure.
(Discussion held off the record.)
BY MR. BENTLEY:
Q. Doctor, when you removed Prolift mesh or Prolene Soft mesh from women that were suffering complications, did you ever send any of those --
MR. BENTLEY: Let me rephrase that.
Q. When you removed mesh because a woman was suffering from complications after Prolift or Gynemesh PS and you sent that to a pathologist, did you ever request any further analysis besides the gross examination?
A. No, I didn't. I sent to what

Page 215

they would do. I didn't request them not to do it, but they traditionally do not do one.
Q. Do you think it's appropriate to sell a product that hasn't been approved to be marketed for a permanent implant in a woman's body?
MR. ROSENBLATT: Object to form.
Did you say "approved" or "cleared"? I just didn't hear it correctly.
MR. BENTLEY: We did approved. We'll do cleared next.
MR. ROSENBLATT: All right.
MR. BENTLEY: Thank you.
A. Do I? Excuse me, say that again.
Q. Do you have an opinion as to whether it's appropriate for a company, a medical device manufacturer, to market a product for the permanent implantation in a woman's body that hasn't been cleared for marketing?
MR. ROSENBLATT: Object to form.

Page 216

A. So, my understanding is that Gynemesh PS was approved to be placed transvaginally, and that was what was used in the Prolift and that's why Ethicon went ahead and did -- and did marketing on it.
Q. So you understand that the Prolift was marketed and sold before it was cleared, right?
A. Well, I -- I -- what I understand is that the FDA requested additional paperwork two years later regarding when the Prolift procedure, when Ethicon submitted something and they went ahead and submitted and they got the approval.
Q. And my question is more narrow, and I doubt that this gets in.
But, assuming you are testifying to regulatory compliance, do you think it's appropriate for a company to market a device that hasn't been cleared for marketing for permanent implantation?
A. So, I think it was cleared that the trocars and the implantation devices

Page 217

were not cleared. So I did not have a problem with the mesh being marketed.
Q. Right. And my question is a little different.
If a device hasn't been cleared for marketing, with that assumption, do you think it's appropriate for a medical device company to market it for the permanent implantation in women's bodies if it hasn't been cleared appropriately?
A. Once again, I think that it was cleared appropriately because we used the Gynemesh PS transvaginally and this is the same mesh that was being used in Prolift.
MR. ROSENBLATT: Greg, maybe I can help you with this.
We're not putting him up to offer that opinion.
MR. BENTLEY: And the problem is there's a number of opinions in here regarding regulatory compliance and warnings and different stuff and if we go down that road, then --
MR. ROSENBLATT: Okay. Well,

Page 218

then I'll let him keep answering.
MR. BENTLEY: Or not answering.
MR. ROSENBLATT: You can answer however you feel appropriate.
THE WITNESS: I guess we got 22 minutes to do this.
BY MR. BENTLEY:
Q. Doctor, you've offered opinions that you think the speed at which Ethicon rolled out design upgrades or changes to their products was appropriate, right?
A. Yes, I think it was appropriate.
Q. You've opined on the appropriateness of Ethicon's decisions to market products and changes to markets, right?
A. Yes.
MR. ROSENBLATT: Object to form; outside the scope.
BY MR. BENTLEY:
Q. I want you to assume with me that the Prolift kit was not cleared for marketing prior to its introduction to the market, okay?

Page 219

A. The kit was not approved. The mesh was.
Q. Right. And so, assuming the kit's not approved, is it appropriate for a company to market it for the permanent implantation in women's bodies?
MR. ROSENBLATT: Object to form.
I just want to caution counsel that he is not offering an opinion, but since he's eliciting one, then you're free to answer.
A. I think it's appropriate for whatever the FDA decided to do at that point in time, and I would fall back on their recommendations and how they dealt with Ethicon.
Q. Doctor, earlier today we talked about different physicians may have different knowledge, and you had some opinions as to what they should know.
Remember that?
A. Yes.
Q. Just very limited questioning here.

Page 220

Regarding complications for prolapse repair, do you have any additional basis for opining as to what physicians know? Is there any study or something that would be different from what we talked about earlier?
A. I can -- we can discuss what's in the AUGS requirement for residents on grafts and what --
Q. And that's what they should know, right?
A. I'm not aware of any particular study of asking what doctors exactly know or don't know.
Q. Doctor, what's your definition of "short-term data"?
MR. ROSENBLATT: Object to form.
A. So, short-term data is anything less than 12 months follow-up as a general rule, but it depends on how long the total follow-up is to figure out what short is.
Q. When you state in your various reports that you're looking for long-term data, you're generally looking for

Page 221

something over one year; is that fair?
A. Yes, that's fair.
Q. There's a couple of different definitions of failure for prolapse treatment that's in the literature and it's discussed in your report. I just want to nail down what you intend to use as your definition for failure in the treatment of prolapse. If you want to refer to page 35, go ahead.
A. So, all the stuff needs to be taken into context. The definitions that we're using today for failure of prolapse has changed, as per my report, from 2001.
So, the way we define failures today is more the composite failure that you were mentioning as opposed to the stricter NIH guidelines that were initially.
Q. So the definition you're adopting is the one from today, the updated definition?
A. When I look at data today, I will use that updated definition.

Page 222

MR. BENTLEY: Doctor, thank you. That is all the questions that I have for now. I may have some follow-up.

MR. ROSENBLATT: Let's take a quick break.

(Recess taken from 8:12 p.m. to 8:22 p.m.)

EXAMINATION BY
MR. ROSENBLATT:

Q. Doctor, my name is Paul Rosenblatt. I represent Ethicon Inc. and Johnson & Johnson.

We're coming up on our ninth hour of deposition testimony.

But, you were asked some questions about various studies in your report.

Do you recall those?

A. Yes, I do.

Q. And some systematic reviews were listed in your report, and others were just on your reliance list, correct?

A. Correct.

Q. For example, a systematic review

Page 223

that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011."

Do you recall reviewing that study?

A. I recall. I don't recall the specifics of the study.

Q. I'll represent that was one of the reviews by the Society of Gynecologic Surgeons.

Do you recall that?

A. Yes.

Q. And I'll represent to you that the Society of Gynecologic Surgeons review from 2011 reviewed 110 studies that reported on erosions with an overall rate of 10.3 percent for synthetic meshes.

My question is is that percentage consistent with the opinions you've offered in your report about the general mesh exposure rate between 10 to

Page 224

12 percent?

A. Yes, it is.

Q. And the Abed systematic review also noted that dyspareunia was described in 70 studies for a rate of 9.1 percent, and my question to you is is that figure generally consistent with the 10 to 15 percent that you offered or that you testified to in your deposition?

A. Yes.

MR. BENTLEY: Objection; misstates.

BY MR. ROSENBLATT:

Q. Doctor, you were also asked about why the ACOG opinion number 513 wasn't specifically called out in your report.

Do you recall that?

A. I do recall that.

Q. I'm showing you your reliance list.

Do you see that ACOG committee opinion on your reliance list?

A. Yes, I do.

Page 225

Q. And you have hundreds of citations in your actual report, do you not?

A. Yeah, I don't remember the exact number, but --

Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair?

A. No, I did not.

Q. And so for example, another systematic review by Schimpf titled "Graft in mesh use in transvaginal mesh prolapse repair. A systematic review from 2016," was that also a systematic review that you relied upon in forming your opinions?

A. Yes.

Q. Doctor, I want to refer you to Exhibit 16.

A. Okay.

Q. This was the Dandolu study --

A. Yes.

Q. -- we spent a good deal of time

Page 226

on.
I want to come back to this, but I just want to read something in the "Discussion" section that states: "Pelvic pain and dyspareunia are well-known complications of the pelvic organ prolapse procedures."
Do you see that?
A. Yes, I do. That's correct.
Q. Is that statement generally consistent with your opinion about which complications are well-known or commonly known to pelvic floor surgeons?
A. Yes, it is.
Q. I'm going to come back to that, Doctor.
I want to show you Exhibit 6. This was the proposal, and you see your name listed number 3 there?
A. Yes, I do.
Q. Did you sign anything on this document?
A. No, I did not.
Q. I want to show you Exhibit 7

Page 227

where you're listed as a subinvestigator.
A. Correct.
Q. And under the staffing, what is your -- if you just take a moment to read that highlighted section there under "Staffing."
A. "She stated that Dr. Harvey Winkler -- she stated that Dr. Harvey Winkler was now the PI. However, upon further discussions during my site monitoring visit, it has been further clarified through documentation of the IRB and with Ms. Iger that Dr. Lind remains the active PI who meets and reviews all study patients. Dr. Winkler has been added as a subinvestigator during any time that Dr. Lind is absent. Dr. Winkler and Dr. Cynthia Hall have seen patients. Dr. Hall has consented patients and both Drs. Winkler and Hall have performed study procedures and exams."
Q. So, my question to you, Doctor, is would it be fair to say that you may not have specifically recalled this IRB

Page 228

study because you were not, in fact, the primary investigator?
A. I was not the primary investigator, and I did not recall this particular study.
Q. And Exhibit 8 under the "Conclusion," could you read what it states there?
A. "Pelvic organ prolapse repair using vaginally-placed Gynemesh PS is safe with few mesh-related complications. Most that did occur were successfully treated in the office. Overall at one year success rate was 84 percent."
Q. Is that conclusion based on the Gynemesh PS study that involved Dr. Lind and yourself as a subinvestigator generally consistent with your opinions about Gynemesh PS?
A. Yes.
Q. I want to hand you, hopefully counsel has the marked version since I'm out of copies here, but Exhibit 21.
(Exhibit Winkler 21, Gynemesh PS

Page 229

Early Clinical Experience, was marked for identification, as of this date.)
BY MR. ROSENBLATT:
Q. Exhibit 21, you cite this as reference 15 in your report?
A. Say that again. I was looking at this. I apologize.
Q. So, in your report on page 13, you reference a Gynemesh white paper as reference number 15. It's on page 13.
A. Yes.
Q. And that would be referring to what I've marked as Exhibit 21.
And do you see Dr. Lind's name there as an investigator?
A. Yes, I do.
Q. Would it be --
MR. BENTLEY: I'm sorry, what page are you on?
MR. ROSENBLATT: Of the report?
MR. BENTLEY: You're on the exhibit?
MR. ROSENBLATT: Yes.

Page 230

BY MR. ROSENBLATT:
Q. Then on page 14 of your report, there are some mesh characteristics and a photograph of Gynemesh PS.
Do you see that?
A. Yes, I do.
Q. Do you recognize whether or not those photographs are consistent with the photographs depicted in this study?
A. Yeah, they're identical in the study as in my report.
Q. Doctor, I want to hand you what's been marked as Exhibit 22.
(Exhibit Winkler 22, color copy photograph, was marked for identification, as of this date.)
BY MR. ROSENBLATT:
Q. Is this a photograph that you brought with you to this deposition?
A. Yes, it is.
Q. Could you just describe for the jury what's depicted in this photograph?
A. So, we can see that there's a mesh on the top of the vagina. So we're

Page 231

looking on an abdominal incision down. There is a probe in the vagina pushing that -- the vagina up, and we can see that there's a mesh placed there on top of the vagina.
This was a transvaginally-placed mesh, a Perigee mesh that I recall, where the patient had a subsequent apical failure and then I went back - not by me, if I remember correctly - and then I went back in to do the recurrent prolapse procedure on her.
And as you can see here, we don't get to see this very often of how transvaginally mesh is placed in patients who are not having complaints. There does not seem to be any contraction, roping, pulling, banding of the transvaginally-placed mesh.
Q. And do you recall being asked questions about changes to the pore geometry?
A. Yes, I do.
Q. And do you see any significant

Page 232

changes to the pore geometry depicted in this photograph?
A. No, I do not.
Q. Doctor, looking at Exhibit 15, the ACOG committee opinion number 513.
A. Okay.
Q. I want you to pull out Exhibit 15 as well.
A. Got it.
Q. And also if you could refer to page 16 of your report.
A. Okay.
Q. And on page 16, you write: "The rationale for me was to use permanent mesh for patients who had failed a prior prolapse procedure or for post-hysterectomy patients with prolapse who were poor candidates for or did not desire an abdominal procedure."
Do you see that?
A. Yes, I do.
Q. Is that generally consistent with the description, as you understand it, in the ACOG practice bulletin about

Page 233

patient selection?
A. Yes, it is.
Q. Specifically in the ACOG practice bulletin, the second bullet point on the last page states: "Pelvic organ prolapse vaginal mesh repair should be reserved for high risk individuals in whom benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly of the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures."
Do you see that?
A. Yes, I do.
Q. And is that generally consistent with what you were telling counsel about discussing the risks and benefits for each patient?
A. Yes, it is.
Q. And you're certainly not here to tell the jury that pelvic mesh should be used as the primary procedure for every single patient who has pelvic organ

Page 234

prolapse, are you?
A. No.
Q. And do you rely on a company to provide specifics on patient selection, or do you rely primarily on your surgical experience, practice bulletins, and other medical literature?
A. I rely on my experience and the medical literature predominantly.
Q. And why do you not rely on a company to tell you how to practice medicine?
A. A company hasn't gone to medical school, hasn't seen patients, hasn't done a residency and a fellowship, and operate.
Q. On page 3 of the ACOG practice bulletin, it states: "Pelvic pain, groin pain and dyspareunia can occur with pelvic reconstructive surgery regardless of the use or non-use of mesh."
Do you see that?
A. That is correct.
Q. And is that generally consistent with your opinions about the commonly

Page 235

known risks of all prolapse procedures?
A. Yes, it is.
Q. Doctor, if you could pull out Exhibit 16, that is the Dandolu study again.
A. Yes.
Q. Now, in your report you cite the study on page 33?
A. Yes, I do.
Q. And if you look on page 32, what is the specific heading of that section?
A. "Transvaginal mesh and pain."
Q. So, is that what you meant when you said you were citing the data specific to transvaginal mesh and pain as it applied to this section of your report?
A. Yes, I do.
Q. And the results state: "Mesh removal/revision was reported highest in transvaginal mesh repair at 5.1 percent."
Do you see that?
A. Yes, I do.
Q. And is that percentage generally consistent with your understanding of the

Page 236

removal/revision rate?
A. Yes, it is.
Q. If you turn to table 3.
Well, Doctor, before we go to table 3, you're not suggesting to the jury that when you account for revisions associated with mesh erosion or exposure that a vaginal mesh repair has a lower rate of reoperations overall compared to native tissue repairs, are you?
A. I'm not saying overall that transvaginal mesh has a lower reoperation rate, correct.
Q. In fact, you offered that opinion in your report when you cited to the 2006 Maher Cochrane review where you describe their findings about increased total reoperation rates?
A. Correct.
Q. And we'll jump around a little bit, but on page 21 of your report.
A. Yes.
Q. It states: "The 2016 Cochrane review found that, quote, there was no

Page 237

evidence of a difference between the groups in rates of de novo dyspareunia, end quote. Additionally, the review noted that recurrence and rates of repeat surgery for prolapse were both lower in the mesh group, although more women in the mesh group required repeat surgery for the combined outcome of prolapse, stress incontinence, or mesh exposure. It is of no surprise that using a composite group for repeat surgery that includes mesh exposure will be higher in the mesh group."
Do you see that?
A. Yes, I do.
Q. And is that generally consistent with the findings that are described in Dandolu about an increased total reoperation rate?
A. That's consistent, yes.
Q. And jumping back to Dandolu table 3, it shows common associated diagnoses during follow-up, and then it has dyspareunia and pelvic pain on that chart.

Page 238

Do you see that?
A. I do see that.
Q. Which was higher for dyspareunia, the native tissue repair or the transvaginal mesh repair?
A. The native tissue repair.
Q. And does the native tissue repair show 7.5 percent compared to 6.1 percent?
A. Yes, it does.
Q. And which was higher, the native tissue repair or the transvaginal mesh repair, for pelvic pain?
A. The native tissue repair was higher at 22 percent versus 16.4 percent.
Q. And counsel suggested that there might be some cherry picking.
You're certainly not offering these numbers to say that pain and dyspareunia are higher with native tissue repairs as they appear in this report, but just that overall the studies show that there's no significant difference; is that fair?

Page 239

MR. BENTLEY: Object to colloquy. Object to form; leading; compound; vague.
A. Yes.
MR. ROSENBLATT: That's a record.
MR. BENTLEY: Speculation; misstates.
BY MR. ROSENBLATT:
Q. Doctor, you also cited some other reviews in your expert report. I'd like to hand you now what I've marked as Exhibit 17, which is the Diwadkar systematic review.
(Exhibit Winkler 17, Diwadkar article, was marked for identification, as of this date.)
BY MR. ROSENBLATT:
Q. Are you familiar with this study?
A. Yes, I am.
Q. And again this is a systematic review?
A. Yes, it is.

Page 240

Q. And it's titled "Complication and Reoperation Rates After Apical Vaginal Prolapse Surgical Repair"?
A. Correct.
Q. And if you look at table 2, and you look at the dyspareunia rates for traditional vaginal repair, sacrocolpopexy and mesh kits, do you see any significant differences?
A. There are no significant differences between the three.
Q. And if you look at the total complication rates as reported on this chart in the systematic review, do you see any significant differences?
A. No, I do not.
Q. Is that chart describing the complications generally consistent with your opinions as it relates to dyspareunia and total complications?
A. Yes, it does.
Q. I'm handing you now what's been marked as Exhibit 18, which is a systematic review by Maher titled

Page 241

"Anterior Vaginal Compartment Surgery."
(Exhibit Winkler 18, Maher article, was marked for identification, as of this date.)
BY MR. ROSENBLATT:
Q. Do you see that?
A. Yes, I do.
Q. And the aim of this study was to review the safety and efficacy of anterior vaginal compartment pelvic organ prolapse surgery, and they described their methodology as reviewing English language scientific literature after searching Pub Med, Medline, Cochrane library and the Cochrane database of systematic review published up to January of 2012.
Do you see that?
A. Yes, that's correct.
Q. It states: "Consistent Level I data support a superior anatomical outcome for polypropylene mesh compared with a biological graft in the anterior compartment."
Do you see that?

Page 242

A. Yes, I do.
Q. Is that generally consistent with your opinions?
A. Yes, it is.
Q. And in all fairness, it says: "Mesh exposure rate was significantly higher in the polypropylene mesh group"?
A. Not surprising. Agreed.
Q. It goes on to state: "Consistent Level I evidence demonstrates superior subjective and objective outcomes following anterior transvaginal polypropylene mesh as compared to anterior colporrhaphy."
Do you see that?
A. Yes, I do.
Q. And what grade did they give that conclusion?
A. Grade A.
Q. Is that generally consistent with the literature, at least as reported in 2013?
A. Yes, that I'm aware of.
Q. And a little further down it

Page 243

states: "Anterior polypropylene mesh had a mesh extrusion rate of 10.4 percent with 6.3 percent requiring a surgical correction."
Do you see that?
A. Yes, I do.
Q. And is that generally consistent with the opinions you've offered here today?
A. Yes, it is.
Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior polypropylene transvaginal mesh."
Do you see that?
A. Yes, I do.
Q. And is that generally consistent with your opinions?
A. Yes, it is.
(Exhibit Winkler 19, Sokol

Page 244

article, was marked for identification, as of this date.)
BY MR. ROSENBLATT:
Q. Doctor, I'm going to hand you what's been marked as Exhibit 19, which is the "One-Year Objective and Functional Outcomes of a Randomized Clinical Trial of Vaginal Mesh For Prolapse," by lead author Andrew Sokol.
A. Yes, I see it.
Q. Are you familiar with this study?
A. Yes.
Q. And this is a follow-up to the Iglesia study; is that correct?
A. That's correct.
Q. And this study compares Prolift to anterior colporrhaphy?
A. Correct.
Q. Now, on page 86.e6 they state: "Of the 32 mesh subjects being Prolift, five women or 15.6 percent had mesh exposures."
Do you see that?

Page 245

A. Yes, I do.
Q. And it describes the exposures occurred at two weeks, six weeks, and subpoint 5 weeks and 2.1 months and were located along incision lines in the anterior compartment and posterior compartment in two cases?
A. Yes, I see that.
Q. Is that generally consistent with your opinions that most exposures will occur at the incision line?
A. That's correct.
Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct?
A. That's correct.
Q. They continued following the patients. They just stopped --
A. They just stopped enrolling.
Q. And a little further in the paper it states: "Of the 33 no mesh participants, five women, or 15 percent, had apical Gore-Tex suture exposures."

Page 246

Do you see that?
A. Yes, I do.
Q. So, although the investigators stopped the study because the exposure rate with the Prolift surpassed the predefined 15 percent, it would be correct to say that so did the suture exposures with the native tissue repairs, correct?
A. It would be correct to say that, yes.
Q. And a little further down some of the findings were that: "There were no statistically significant differences were found between the mesh and no mesh groups with respect to long-term complications."
Do you see that?
A. Yes, I do.
Q. And a little further down it states: "No statistically significant differences were found between the mesh and no mesh groups with respect to new onset dyspareunia. The mesh group 1 in 11 women, or 9.1 percent, versus no mesh group 3 out of 14 women, 21.4 percent."

Page 247

Do you see that?
A. Yes, I do.
Q. Is that generally consistent with the opinions you've offered in your report and here today?
A. Yes, it is.
Q. And in fact, this study actually shows a higher de novo dyspareunia rate with the anterior colporrhaphy compared to Prolift in absolute numbers, correct?
A. Yes, that's accurate.
Q. But you're not here offering the opinion that the dyspareunia rate is higher with native tissue repairs, are you?
A. No, I am not. They're equivalent, is my opinion.
Q. And so, if counsel wanted to accuse you of cherry picking, you could have very easily pulled those numbers out to say that the mesh exposure --
MR. ROSENBLATT: Strike that.
Q. Look at Exhibit 10, which is the Dietz and Maher review on pelvic organ

Page 248

prolapse and sexual function.
Do you see that?
A. Yes, I do.
Q. What were their results?
A. With regard to the anterior compartment, the use of mesh is associated with neither a worsening in sexual function, nor an increase in de novo dyspareunia compared with traditional anterior colporrhaphy.
Q. Is that generally consistent or inconsistent with your opinions?
A. That's consistent with my opinions.
Q. Doctor, you testified earlier that it's somewhat difficult to study or capture true de novo dyspareunia rates in studies.
Can you just explain why that is for the jury?
A. So, dyspareunia rates are dependent on several variables. Age has something to do with it. Menopause has something to do with it. Your overall

Page 249

well-being has something to do with it, as well as the psychosocial situation with your partner. We know that as women age, the dyspareunia de novo rates increase, and overall, however, as women are getting older, they're having decreased sexual activity.
Q. Thank you, Doctor.
Now I want to look at Exhibit 12, which is the study by Damoiseaux, D-A-M-O-I-S-E-A-U-X.
This is a seven-year Prolift study that you were asked about.
A. Correct.
Q. I want to show you in the conclusions they state: "Although the mesh exposure rate was extremely high, we found no difference in pain rate or dyspareunia between the two groups."
Do you see that?
A. Yes, I do.
Q. And then a little above that in table 3 they report complications comparing mesh versus conventional

Page 250

procedures.
A. That is correct.
Q. And when looking at mesh versus the conventional procedures, which was higher with respect to percentage of pain?
A. It was higher in the conventional procedure 45 percent as opposed to 34 percent in the mesh group.
Q. And what about chronic pelvic pain?
A. Also higher in the conventional group, 29 percent as opposed to 15 percent.
Q. And what about de novo pelvic pain?
A. Higher in the conventional group than the mesh group.
Q. And in all fairness, dyspareunia?
A. Dyspareunia was slightly higher in the mesh group, but at 27 to 25 percent.
Q. And de novo dyspareunia?
A. Was also fairly equivalent at 10

Page 251

percent in the mesh group and 12 percent in the conventional group.
Q. And although this study shows that the conventional group had higher rates of, for example, chronic pelvic pain and de novo dyspareunia, you're not using this study to say that native tissue or conventional prolapse repairs have higher rates of pain and dyspareunia, are you?
A. Absolutely not.
Q. And so if you wanted to cherry pick studies, this could be an example of where you could use percentages to your advantage, right?
A. That is correct.
Q. But rather than doing that, could you explain why, in fact, you rely on Level I literature as opposed to just pulling rates from one study?
A. Right. So, from one study is not as good of a study and as high a level as a composite from multiple studies in using that data to try to get higher level results.

Page 252

Q. Doctor, in the Altman study that was marked as Exhibit 11, counsel went over with you on page 1832 that pain during sexual intercourse was reported to occur usually or always by 2 percent of the women after colporrhaphy and by 7.3 percent after transvaginal mesh surgery with Prolift and the p-value is 0.07.
Do you see that?
A. Yes, I do and that's nonsignificant.
Q. Explain what it means when something is not statistically significant.
A. So, it has to -- that number has to happen more by chance, and if we don't see a number of less than 0.05, we cannot say that that result happened just by chance.
Q. And based on your review of systematic reviews and the Level I literature and randomized controlled trials, what is your understanding as to whether or not there's any statistically

Page 253

significant difference in postoperative complications, such as de novo dyspareunia or de novo pain, comparing transvaginal mesh to native tissue repairs?
A. I'm not aware of studies that show that there is a statistically significant difference between the two.
Q. But would it be fair to say that the Level I literature demonstrates that there are no statistically significant differences?
MR. BENTLEY: Objection.
A. Most importantly it's the Level I data that I rely on that shows that there is no statistically significant difference between the two.
Q. And is that consistent with your opinion based on Exhibit 9, which is the 2016 Maher Cochrane review where on page 18 it states: "There was no evidence of a difference between the groups in rate of de novo dyspareunia"?
A. That is correct. And that's what I based my previous answer on no

Page 254

difference on the Level I studies.
Q. And was it also true for their findings about sexual function and quality of life?
A. That is true.
Q. Doctor, you were asked about Exhibit 13, which is the Lowman study titled does the Prolift system cause dyspareunia?
A. Yes.
Q. I think you tried expanding on your answer about the conclusion of the study, and I'd like you to take the opportunity to finish what you were trying to say.
A. Eighty-three percent of respondents with de novo dyspareunia would have had -- would have the procedure done again.
Q. And what does that indicate to you about patient satisfaction or subjective cure in this study?
MR. BENTLEY: Objection.
A. That indicates to me that

Page 255

patient satisfaction was high.
Q. Looking at table 4, what does that table indicate to you about all the different procedures listed there and the rates of de novo dyspareunia?
A. So, in this particular study, the rates of de novo dyspareunia after abdominal sacrocolpopexy were 14.5 percent. Sacrospinous ligament suspension 36.1 percent. Uterosacral suspension 25.9 percent. APR is anterior repair.
Q. Is that anterior and posterior?
A. Anterior and posterior repair 19 percent. And Prolift at 16.7 percent.
Q. Again, although Prolift at 16.7 percent is lower than some of the other figures here, you're certainly not cherry-picking that and suggesting to this jury that rates of de novo dyspareunia are consistently lower with Prolift compared to native tissue repairs, are you?
A. Absolutely not. They're equivalent.
Q. Doctor, I want to show you

Page 256

what's been marked as Exhibit 14. This is the Halaska randomized control trial evaluating Prolift compared to sacrospinous ligament fixation.
Do you see that?
A. Yes, I do.
Q. And do you see where they state in the results: "No difference in quality of life improvement as well as de novo stress urinary incontinence and no overactive bladder onset was found."
Do you see that?
A. Yes, I do.
Q. And is that generally consistent with your opinions about there being no difference in quality of life improvement comparing the different prolapse procedures?
A. Quality of life has been the same with the -- with the procedures, yes.
Q. And the conclusion was: "Mesh exposure occurrence was balanced against a lower prolapse recurrence rate in patients undergoing mesh surgery compared with

Page 257

those undergoing sacrospinous ligament fixation.
Do you see that?
A. Yes, that's correct.
Q. If you could just describe how you take into account the risk-benefit analysis for a more durable repair versus the potential complication of mesh exposure.
A. So, I have a discussion with my patient of if we're going to use a transvaginal mesh we may get improved durability of the repair. If we use a transvaginal mesh, understanding that there is an exposure rate that occurs when you use a transvaginal mesh, and some of those patients may elect to go back to the operating room for a revision.
Q. Doctor, the study reports a one-year mesh exposure rate of 20.8 percent.
A. That is correct.
Q. Of that 20.8 percent, how many of those were symptomatic mesh exposures?

Page 258

A. One-quarter of them were symptomatic.
Q. And what does that mean that -- what is the difference between symptomatic versus asymptomatic?
A. So, in the symptomatic patients, the mesh exposure was bothering them, and in the asymptomatic exposures, it was not bothering them.
Q. Doctor, do you see under the comments where it states: "However, a significant difference in the recurrence rate was found between the groups favoring the mesh group 12 months after surgery"?
A. Yes, I see that.
Q. And would you say generally throughout the medical literature, at least with respect to the anterior compartment, the recurrence rates are significantly lower when a mesh repair is undertaken compared to a native tissue repair?
A. Yes.
Q. Do you see in the study where

Page 259

they showed no significant differences were observed and changes in quality of sexual life between sacrospinous fixation and mesh groups as measured by the PISQ short form?
A. Yes, I do see that.
Q. Does that finding surprise you at all?
A. No, it does not.
Q. Doctor, you were asked again about your reliance list, and I think you testified that you reviewed some of plaintiff's expert reports?
A. Yes.
Q. And did you also review the documents and studies that they cited in the body of those reports?
A. Yes.
Q. Doctor, do you practice medicine based on --
MR. ROSENBLATT: Well, strike that.
Q. Doctor, you were asked about whether or not you have any criticisms of

Page 260

the type of data plaintiff's experts rely upon.
Do you practice medicine based on internal documents?
A. No, I do not.
Q. In residencies and fellowships, do they teach based on internal company documents, or is it primarily based on evidence-based medicine and the medical literature?
A. It's based on the medical literature.
Q. We previously discussed your consulting experience.
You did, in fact, consult with Ethicon on the design of Gynemesh PS?
A. I discussed with them on design of transvaginal mesh. I don't know if they told me it was on Gynemesh PS or not.
Q. I think you said Prolene Soft mesh and Gynemesh PS are the same mesh?
A. Yes.
Q. You said you used those from 2002 to 2011, approximately?

Page 261

A. So, I used the Gynemesh PS -- are we talking about in my abdominal sacrocolpopexies are we talking about?
Q. Just in general in your practice.
A. Yes, somewhere around there.
Q. Now, if you would have switched from one product to another, for example if you went from Gynemesh PS to a Boston Scientific Y-mesh, were you doing so because of concerns of safety?
A. No, I was not. When doing it robotically, it's just easier to do it with a Y piece of mesh in my hands as opposed to two separate pieces of mesh.
Q. And before you started doing Prolift, were you already familiar with the anatomical landmarks of that procedure?
A. Yes, I was.
Q. How so?
A. I already was placing transobturator slings. I had already been trained on the Perigee and Apogee meshes.

Page 262

So I was familiar with the anatomy.
Q. I believe you testified that your practice has changed somewhat in terms of you're now offering --
MR. ROSENBLATT: Well, strike that.
Q. Doctor, I believe you are implanting less transvaginal mesh now than you were within the past decade; is that fair?
A. That's accurate.
Q. What impact do you think the litigation and the fear from advertisements has had on your practice?
MR. BENTLEY: Objection.
A. So, the -- almost every single patient that I see and talk to has seen or heard about the litigation or something advertised on television, and they -- we have a discussion about what that involves, but I don't think there's any human being in New York that hasn't seen those advertisements.
Q. Doctor, the Prolift surgeons

Page 263

monograph that you reference in your report describes a dyspareunia rate of 6 to 9 percent.
Is that generally consistent with your understanding of the dyspareunia rates as reported in 2007?
A. Yes, it is.
Q. Doctor, we talked a lot about reoperation rates.
That doesn't necessarily take into account failures though, does it, prolapse failures?
A. The reoperation rate includes failures and exposures and everything.
Q. But a patient with a native tissue repair may have a failure or recurrence, but just decides they don't want to undergo another procedure for prolapse, so that could be a patient where -- who failed a native tissue repair, but wouldn't undergo another operation?
A. That is correct.
Q. And have you seen that in your

Page 264

practice?
A. Absolutely.
Q. You were asked some about the different properties of the meshes and how the fiber size is slightly larger with TVT compared to Gynemesh PS.
Would you expect the pore sizes to be much larger for TVT, which is only 1 centimeter wide?
MR. BENTLEY: Objection.
BY MR. ROSENBLATT:
Q. The mesh itself is only 1 centimeter wide --
A. Correct.
Q. -- for TVT, right?
A. So you don't have that much room to make the pores bigger.
Q. In the one patient that you described that had bunched mesh, did you attribute that to any defect in the mesh?
A. No, I did not.
Q. Are all the opinions that you've offered here today and in your report held to a reasonable degree of medical

Page 265

certainty?
A. Yes, they are.
MR. ROSENBLATT: No further questions at this time.
FURTHER EXAMINATION BY MR. BENTLEY:
Q. Doctor, your reliance list describes the documents reviewed --
THE WITNESS: Just give me one second.
(Discussion held off the record.)
BY MR. BENTLEY:
Q. Your reliance list, Doctor, lists the documents you reviewed and relied upon to reach your opinions in this case, right?
A. Yes.
Q. And on that list there's a number of company documents you reviewed and relied upon to reach your opinions here, correct?
A. That's correct.
Q. And you testified that in your medical practice, you don't rely upon

Page 266

company documents, do you?
A. I don't rely on company documents to tell me how to do surgery, no.
Q. So it's slightly different here in reaching your litigation opinions, you did rely upon and review company documents, right?
MR. ROSENBLATT: Object to form to the extent you're saying he's relied upon.
A. I may have reviewed them, but I did not include the company documents in my medical opinions of the mesh or the procedure.
Q. They're on your reliance list though, right?
A. They're on the reliance list.
Q. Doctor, you said you don't rely upon a manufacturer to provide you information about the products; is that correct?
MR. ROSENBLATT: Object to form; mischaracterization.

Page 267

A. I don't rely on a manufacturer to give me information regarding -- I don't rely on manufacturers to tell me how to do surgery.
Q. So in your medical practice, you don't rely upon information provided by the manufacturers?
A. One of the things that I may rely on with regarding surgical procedures that I'm using a device in, yes, I can look to see what the company provides, but I may not decide my ultimate decision based solely on what the company provides.
Q. So you do rely upon the information they provide or you don't?
A. I review it. I don't want to say I solely rely on that.
Q. In redirect, counsel asked you about a study, I think it was the Dandolu, and it mentioned that surgeons were aware of the complication dyspareunia and pain; is that correct? Do you remember that?
A. I think that surgeons should be aware of pain and dyspareunia when they're

Page 268

performing prolapse procedures.
Q. Specifically limited to that study.
Do you remember reading the quote that said surgeons were aware of these complications, including dyspareunia and pain?
A. It says: "Pelvic pain and dyspareunia are well-known complications of the POP procedures."
Q. That's great.
And it doesn't say the frequency of transvaginally implanted mesh is well-known, does it?
Is the word "frequency" in that sentence?
A. The word "frequency" is not in the sentence.
However, transvaginal mesh is a component of pelvic organ prolapse repair surgeries. You can't separate the two out.
Q. Doctor, earlier today we went through your TVT report, and in your TVT

Page 269

report, you quoted from ACOG and AUGS, didn't you?
A. Yes, I did.
Q. But you didn't quote it in your Prolift report, right?
A. I didn't use a direct quote.
However, I referenced to that report.
Q. What was your methodology for deciding not to quote the ACOG/AUGS committee opinion in this report?
A. It didn't give absolute numbers, if I remember correctly, on incidences of pain and dyspareunia and one versus the other.
Q. One of the explanations you gave for not citing the other findings in Dandolu that were not included in your report was you included Dandolu under your section on page 33 about abdominal mesh and pain; is that correct?
MR. BENTLEY: I apologize. Let me rephrase that.
Q. You include Dandolu on page 33

Page 270

under your section for transvaginal mesh and pain and you didn't provide the other finding from Dandolu.

And your explanation for that was this was a section just about transvaginal mesh and pain, right?

A. That's correct.

Q. But your report, of course, discussed the other findings from Dandolu in other sections, right, reoperation rate failure, that type of stuff?

A. I didn't reference Dandolu, but we, once again, have -- I admit there is a reoperation rate with transvaginal mesh.

Q. Right.

A. It is --

Q. My question very specifically is you cited Dandolu under one section, right? You provided one finding from Dandolu?

A. Right.

Q. And your explanation for why you didn't discuss any of the other findings from Dandolu was that Dandolu citation was

Page 271

in one specific subsection in your report, right?

A. Right.

Q. But my question is the other findings in Dandolu --

A. I did cite the Level I evidence of reoperation rates in my report.

Q. But you didn't cite the other findings from Dandolu elsewhere in your report where you discussed those sections?

A. Dandolu's findings would likely be included in the Cochrane review, if it was available at that time.

Q. Doctor, what are the potential adverse events that are commonly associated with surgically implantable materials such as Gynemesh PS?

A. Infection, inflammation, adhesion formation, fistula formation, erosion, extrusion, and scarring that results in implant contraction.

Q. What are you reading from, Doctor?

A. I'm reading from page 17 of my

Page 272

report.

Q. And what is that?

A. It lists the adverse events in the IFU on Prolift.

It also has: "Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during Gynecare Prolift guide passage and may require surgical repair."

Q. And my question wasn't what's cited from the IFU in your report.

It was what are the common adverse events that you think are known regarding implantable mesh for the treatment of prolapse?

A. Exposure, erosion, damage to other organs, dyspareunia, chronic pelvic pain, adhesions, scarring.

Q. Right. And you think those -- it's your opinion that those have been known since -- when were those complications known?

A. Pain and dyspareunia and all these -- all the complications except for

Page 273

exposure are commonly associated with pelvic organ prolapse procedures.

Q. Okay. I believe you included a screen shot from Exhibit 21 in your report, and the adverse events from that marketing piece don't include complications such as dyspareunia and chronic pain, do they?

A. Once again, we agreed that it was not in the IFU of chronic pain and dyspareunia 'cause it was a commonly known complication which is not required to be placed in an IFU, according to CFR guidelines.

Q. I'm sorry, that wasn't my question.

In the exhibit that you're holding in your hand, it lists complications commonly known.

It doesn't include dyspareunia and chronic pain, does it?

A. This particular piece of paper does not include that.

MR. BENTLEY: Thank you. No

further questions.

MR. ROSENBLATT: I've got none.

(Deposition adjourned at 9:20 p.m.)

A C K N O W L E D G M E N T

STATE OF)
:ss
COUNTY OF)

I, HARVEY A. WINKLER, M.D., hereby certify that I have read the transcript of my testimony taken under oath in my deposition of March 12, 2017; that the transcript is a true and complete record of my testimony, and that the answers on the record as given by me are true and correct.

_____
HARVEY A. WINKLER, M.D.

Signed and subscribed to before me this _____ day of _____, 2017.

_____
Notary Public, State of

E R R A T A

PAGE / LINE / CHANGE / REASON

C E R T I F I C A T E

STATE OF NEW YORK
COUNTY OF NEW YORK

I, Marie Foley, RMR, CRR, a Certified Realtime Reporter and Notary Public within and for the State of New York, do hereby certify:

THAT HARVEY A. WINKLER, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 15th day of March, 2017.

_____
MARIE FOLEY, RMR, CRR

LAWYER'S NOTES

PAGE / LINE